WHO/CDS/CSR/ISR/99.4

A Standard Verbal Autopsy Method for Investigating Causes of Death in Infants and Children

World Health Organization
Department of Communicable Disease Surveillance and Response

The Johns Hopkins School of Hygiene and Public Health

The London School of Hygiene and Tropical Medicine

A Standard Verbal Autopsy Method for Investigating Causes of Death in Infants and Children

by

Martha Anker[1]
Robert E. Black[2]
Christopher Coldham[3]
Henry D. Kalter[2]
Maria A. Quigley[3]
David Ross[3]
Robert W. Snow[4]

[1] World Health Organization.
[2] Johns Hopkins University.
[3] The London School of Hygiene and Tropical Medicine.
[4] Oxford University and the Kenya Medical Research Institute.

(Authors listed in alphabetical order)

Acknowledgements

The authors would like to acknowledge the following collaborators for their invaluable contributions to the validation studies:

United States
Co-investigators: Dr Gilbert Burnham and Dr Randy Kolstad, Johns Hopkins University.

Nicaragua
Project medical supervisors: Dr Natalia Zambrana and Dr Zoyla Segura.

Field work supervisor : Dr Martha Rivas

Project physicians: Dr Martha Rivas, Dr Patricia González, Dr Amelia Tijerino.

Interviewing team: Nadia Lugo, Rosa Maria Pérez, Aurora Mendoza, Oriana Castillo, Yamileth González, Silvia Avellan, Ivania Haar, Avejaneth Saballos, Maria-Ines Leiva and Carlos Aburto.

Data processing staff: Martha Castaño, Sergio Baldelomar and Ernesto Rios.

Directors and staff of hospitals: Manuel de Jesús Rivera (Managua), Velez Paiz (Managua) and Hilario Sanchez (Masaya); Jeffrey Cassel (director) and Ivania Lopez (administrator) of the Instituto CentroAmericano de la Salud, Managua.

Bangladesh
Dhaka Shishu Hospital
Co-investigators: Dr Mohammad Hanif, Dr Naila Z. Khan, Dr Samir Saha.
Project manager : Dr Munir Hossain.
Study physicians: Dr Pervez and Dr Shameem.

Infectious Disease Hospital, Dhaka
Co-investigator : Dr Md Anwar Ali.
Study physician : Dr Mohiddin.

Uganda
Co-investigator : Dr Nathan Kenya-Mugisha of the ARI/CDD Program, Ministry of Health, Entebbe.

Medical officers: Dr J.F. Keeri, Dr P.A. Mainuka, Dr Monday-Araali and Dr J.Ruhweza.

Medical assistants: Ms Florence Twisige and Mr Robert Mugabo.

Thanks are also due to the following: The staff of Fort Portal Hospital; the Basic Health Services Project in Fort Portal; Dr Walter Kipp and the German Agency for Technical Cooperation (GTZ) in Fort Portal and GTZ/PAS in Kampala; and Dr Rick Glasier.

***WHO ARI Radiology Working Group* :**
Readers of chest X-rays of patients in Bangladesh and Uganda:
Dr G.M.A. Hendry, Edinburgh Sick Children's NHS Trust, Royal Hospital for Sick Children, Edinburgh;
Dr Anthony Lamont, Leicester Royal Infirmary, Leicester, UK;
Dr Heinz Tschappeler, Inselspital Bern, Universitats-Kinderklinik, Bern.

The authors would like to thank the several institutions for their support for the validation studies and the preparation and publication of this report. The authors accept full responsibility for information provided and views expressed in the report. The Department for International Development (DFID), UK supported the Nicaragua validation study and the publishing costs. Oxford University, the Kenya Medical Research Institution, and the Wellcome Trust (as part of their senior Fellows Programme in Biomedical Science #033340) supported the work of Robert W. Snow. The Johns Hopkins Family Health and Child Survival Cooperative agreement with USAID supported work by the Johns Hopkins investigators. WHO, DFID and UNICEF supported overall project coordination. The work of Martha Anker was supported by WHO.

Contents

Chapter 1 Introduction

Very little scientifically based information is available on cause-specific mortality rates for many developing countries. What information does exist is often out of date, applicable only to major urban areas, and not sufficiently disaggregated to differentiate between important population sub-groups. Yet such information is needed for targeting of scarce health resources, especially as high mortality tends to be clustered in particular geographical locations and segments of the population.

A verbal autopsy is a method of finding out the cause of a death based on an interview with next of kin or other caregivers. In order for verbal autopsies to be comparable, they need to be based on similar interviews, and the cause of death needs to be arrived at in the same way in all cases. In recent years, verbal autopsies have been used more widely to provide information on cause of death in areas where civil registration and death certification systems are weak, and where most people die at home without having had contact with the health system. This type of interview is often the only way to find out about the cause of death.

Verbal autopsy has been used for a variety of purposes, all of which require arriving at a diagnosis for the cause of death:

C To provide data on mortality by cause.

C To evaluate health interventions aimed at reducing mortality from specific causes of death, when these interventions are being introduced into a limited geographic area on a trial basis.

C To identify ways to reduce unnecessary deaths. For example, combining a verbal autopsy questionnaire with a household questionnaire asking about steps taken by the family and by the health services during the illness preceding death can make it possible to identify problems relating both to health-seeking behaviour and health service provision.

C To facilitate research into factors associated with mortality from specific causes of death.

This document has been developed to improve the measurement of cause-specific mortality, in areas where medical certification of cause of death is rare. It focuses on the use of verbal autopsies to identify the causes of deaths among infants and children, since these age groups are subject to high mortality rates. The materials presented in this document were developed by a collaborative group of scientists from several institutions including the Johns Hopkins University, the London School of Hygiene and Tropical Medicine, Oxford University, the Kenya Medical Research Institute, and the World Health Organization. The document includes a validated verbal autopsy questionnaire together with a set of standard algorithms for determining major causes of infant and childhood deaths. These algorithms provide a uniform method for analysing the verbal autopsy interviews and assigning the most appropriate cause(s) of death.

The remainder of this document is structured as follows. Chapter 2 consists of background material beginning with a review of the “state of the art” of the verbal autopsy

technique, critically discussing the strengths and weaknesses of different approaches. This is followed in Chapter 3 by a description of the work of the collaborative group in both developing and validating the standard verbal autopsy interview and the algorithms presented in the document. Chapter 3 describes the three field validation studies undertaken in connection with this questionnaire, and presents findings from these studies on the sensitivity and specificity of the verbal autopsy algorithms developed as part of this study.

Chapter 4 contains a description of the standard questionnaire and some general instructions to the interviewer. It includes a section on how this questionnaire can be adapted to local settings, and a section containing simple explanations of medical terms used in the questionnaire.

Annex 1 contains the tables for sensitivity and specificity from the validation studies, and Annex 2 contains the verbal autopsy questionnaire.

Chapter 2 State of the Art

Verbal autopsies are currently used by researchers and policy-makers for ascertaining the cause or causes of death. To date there is no standard questionnaire or coding scheme that is widely accepted, and there are few validation studies to indicate which causes of death are most suitable for investigation by verbal autopsy. The present section briefly reviews the types of verbal autopsy questionnaires and coding schemes available, and provides information on those causes of death that are believed to be most suitable for detection by verbal autopsy.

2.1 *Settings in which verbal autopsies are used*

A number of different methods can be used for identifying deaths in the general population, including vital registration systems, population-based reporting systems, and demographic surveys. No matter what method is used to identify deaths, care must be taken to ensure that all deaths are identified and none are missed.

Vital registration systems often do not have sufficient coverage to provide accurate data in developing countries, although they can be used in developed countries to identify deaths for verbal autopsy follow-up interviews.

Demographic surveillance, where all deaths are reported on a regular basis throughout the year (often once every two weeks) have been used for identifying deaths in some developing countries.[5] A number of longitudinal studies have already set up demographic surveillance systems and many of these have been in existence for many years. The populations of these surveillance systems are often relatively large (for example the population covered by MATLAB in Bangladesh includes 212,000 children). These systems are commonly used to evaluate the impact of new health interventions before they are introduced into a wider population. Verbal autopsies have been applied in a number of such evaluation studies.

However, demographic surveillance systems are expensive to set up and to maintain and therefore they exist in only a limited number of countries. Underlying levels of cause-specific mortality in these areas cannot necessarily be generalized to wider populations. When information about a large geographical area is needed, mortality surveys can be used to identify deaths. These surveys have the advantage of covering a much wider geographical area than the demographic surveillance systems, and therefore allow comparisons to be made among different regions of a country; however, care must be taken to be sure all deaths are reported. One way to do this is with re-interview surveys to identify missed deaths. Failure to enumerate all deaths can result in very misleading results. For example,

[5] Fauveau V. et al. The effect of maternal and child health and family planning services on mortality: Is prevention enough? *British Medical Journal*, 1990, 301:103-107; Bogden et al. The effect of maternal and child health and family planning services on mortality: Is prevention enough? *British Medical Journal*, June 1990, 301:103-107; Greenwood BM et al. Deaths in infancy and early childhood in a well-vaccinated, rural West African population. *Annals of Tropical Paediatrics*, 1987, 7:91-99; Lehmann D. Mortality and morbidity from acute lower respiratory tract infections in Tari, Southern Highlands Province. *Papua New Guinea Medical Journal*, 1991, 34:174-184.

one re-interview survey found that 28% of deaths had been missed by the original mortality survey.[6]

2.2 *Underlying assumptions of the verbal autopsy method*

An underlying assumption of the verbal autopsy method is that each cause of death investigated has a set of observable features that can be recalled during a verbal autopsy interview. Furthermore, it is assumed that the features of one cause of death can be distinguished from those of any other cause of death. From this it follows that diseases like measles and neonatal tetanus, which have very distinctive symptoms, are likely to be more suitable for verbal autopsy diagnosis than systemic diseases such as malaria, which has no particularly distinctive features, and shares many symptoms with other common childhood diseases such as acute lower respiratory infections (ALRI).

The underlying mix of causes of death in the population affects the accuracy of the verbal autopsy. This implies that the accuracy of the estimates will vary according to the population under study. For example, it has been suggested that verbal autopsy may be better able to identify ALRI in malaria-free areas than in areas in which malaria is a common cause of childhood deaths.[7]

In addition, cultural aspects influence the accuracy of verbal autopsy. The willingness to accept a verbal autopsy interview, the ability of the respondent to describe the final illness, and the way in which diseases are understood and described in the community will vary from culture to culture.

2.3 *Open-ended history of final illness versus close-ended questions*

Two different interview methods can be used to obtain a verbal account of the injury or illness that led to death. One method uses an in-depth open-ended history of the final illness. The interviewer asks the mother, next-of-kin or caregiver to tell about the events leading up to death in their own words, and probes freely to follow up particular aspects. This descriptive account is then read by medical experts who code the interview in terms of cause of death. The other interview technique is to ask a series of closed-ended (often pre-coded) questions, which are usually coded using systematic pre-determined algorithms for cause of death.

Most of the early verbal autopsy studies[8] have used the open-ended history approach which requires expert coding. This is probably the easiest way to establish and maintain

[6] Becker SR, Diop F, Thornton JN. Infant and child mortality in two counties of Liberia: Results of a survey in 1988 and trends since 1984. *International Journal of Epidemiology*, 1993, 22(1):S56-63.

[7] Ross DA. *Monitoring cause-specific infant and child mortality rates in areas where death certification systems are weak*, Geneva, World Health Organization, 1992, (unpublished document WHO/ESM/UNICEF/WP/2).

[8] Greenwood BM et al. Deaths in infancy and early childhood in a well-vaccinated, rural West African population. *Annals of Tropical Pediatrics*, 1987, 7:91-99, and Garenne M and Fontaine O, Assessing probable causes of deaths using a standardized questionnaire. A study in rural Senegal. In: Vallin J, D'Souza S, Palloni A (eds). *Measurement and analysis of mortality: Proceedings from the International Union for the Scientific Study of Population meeting held in Siena, July 1987*.

rapport with the respondent, since respondents have a chance to express themselves fully. The questions asked are tailored to the case at hand, so that the respondent is not asked a lot of questions that may be irrelevant to their own particular case, and interviewers can use their judgement about which aspects to follow up with further questions. This format allows the timing and the sequence of events to be easily recorded - and other types of information about the interview, such as the body language, and tone of voice of the respondent, to be taken into account. The open-ended histories, when used as a stand-alone method, need to be conducted by highly trained interviewers, because the questions asked are left to the judgement of the interviewer. Sometimes the interviewers are medical doctors. In any case the interviewers require special training to do the interview. Most studies that use open-ended histories have been coded by medical doctors, since the histories do not easily lend themselves to coding by non-medical persons or by pre-defined algorithms. This requires substantial amounts of time from relatively senior staff and adds a subjective element into the coding process.

Closed-ended questions, which ask about whether specific symptoms and signs have been present during the final illness, are more objective than open history questions. They also lend themselves better to the development of standard pre-defined algorithms for specific causes of death. Coding can be done by computer, since the algorithms are already defined. However, this method has the disadvantage of being relatively inflexible, so that information that has not been included in the questionnaire is lost, no matter how relevant it might be for determining the cause of death in a particular case.

The standard verbal autopsy questionnaire reproduced in Annex 2 uses a combination of an open history question followed by a series of closed ended questions. In this way it takes advantage of each approach. However, the standard questionnaire is coded according to pre-determined algorithms. This is the best way of maintaining comparability across studies.

2.4 *Multiple versus single causes of death*

Many verbal autopsy studies allow only one cause for each death - usually the underlying cause of death. This means that the total number of causes of death is equal to the total number of deaths themselves. This seems intuitively satisfying, and the results are relatively easy to present.

On the other hand, it commonly happens that the death of a child is the result of more than one cause. The standard verbal autopsy questionnaire for children used in the present document allows for multiple causes of death, because it was considered to be impractical to distinguish between underlying and contributory causes of death in a questionnaire used for verbal autopsies in children. The use of a standard questionnaire also avoids the situation where the definition of a disease or cause of death affects the definitions of other diseases or causes of death. For example, if all children who die within one month of having measles were to be counted as deaths due to measles only (which is the WHO standard definition of a measles death), then the other more immediate causes of death such as ALRI or diarrhoea would be under-counted. By allowing multiple causes of death, we do not have to choose between measles and ALRI or diarrhoea as a sole cause of death. This makes intuitive sense, because many children who die from a combination of causes could have survived if any one of the causes of death had been either prevented or treated early enough. One disadvantage of assigning multiple causes by algorithm is that ranking of the importance of causes is not

possible. For example, a death primarily due to diarrhoea with concurrent pneumonia is indistinguishable from a death primarily due to pneumonia with concurrent diarrhoea.

When interpreting the results of a verbal autopsy questionnaire, it is important to know whether multiple causes of death are allowed for in the coding, since the expected proportions of deaths for each cause will generally be higher when multiple causes of death are allowed.

2.5 *Causes of death for which verbal autopsy is best suited*

Verbal autopsy questionnaires and algorithms need to distinguish between different possible causes of death using only information that can be recalled by caregivers. Naturally, verbal autopsy does best at identifying causes of death with distinctive features that are not found in other causes of death. Many injuries fit this requirement well. If a cause of death is characterized only by vague symptoms and signs that overlap with many other causes of death, it is very difficult to identify that particular cause of death accurately when using verbal autopsy.

One way to establish how well a set of verbal autopsy questions and algorithms identify a particular cause of death is to do a validation study in a setting where there is a medical diagnosis for the final illness. Results obtained from a verbal autopsy questionnaire, answered by caregivers of children who died, are compared to the medical diagnosis. In some validation studies, the verbal autopsy questionnaire was administered to all children admitted to hospital with life-threatening conditions, in order to study a wide range of life-threatening conditions existing in the community, and not only the conditions that cannot easily be treated in hospital. This also decreases the amount of time needed for case finding, since survivors of severe illness are included in the study as well. Other studies are restricted to children who died in hospital.

Validation studies in hospital settings have important limitations. First, children taken to hospital and caregivers who take children to hospital may not be representative of the general population in terms of socio-demographic characteristics, health-seeking behaviour, causes and clinical presentation of illness, severity, etc. Secondly, when a child is taken to hospital, or at the time of death or discharge, the caregiver is usually interviewed by the staff and often learns the medical diagnosis (especially when the child dies, when they may be given a copy of the death certificate). This may affect the caregiver's answers to the verbal autopsy questionnaire. None the less, from a practical point of view, hospital validation studies are the only feasible way to validate a verbal autopsy questionnaire.

Table 1 presents values for sensitivity and specificity in previous verbal autopsy studies for some major causes of childhood illness. As expected, the sensitivity and specificity of various algorithms vary widely from study to study, and by cause of death. Some patterns emerge - namely that the levels of sensitivity and specificity for neonatal tetanus, measles, malnutrition, and accidents are generally acceptable, while those for diarrhoea and ALRI are less satisfactory, but still considered good enough for certain purposes. Results for malaria are considered to be unsatisfactory, with the exception of a study in Namibia, where cerebral malaria had reasonable levels of sensitivity and specificity. Possible reasons for such findings across studies are chance, differences in study design and methodology, in cultural setting, in the mix of diseases in the population, in verbal autopsy questionnaires, and in methods of assigning the cause of death.

Table 1. Sensitivity and specificity of verbal autopsies for major causes of childhood death, based on previous validation studies

Cause of death	Country	Study Source	Sensitivity %	Specificity %	Algorithms used
ARI	Philippines	1	66	60	Cough and dyspnoea ≥1 day
	Philippines	1	59	77	Cough ≥4 days and dyspnoea ≥1 day
	Kenya	2	28	91	
	Namibia	3	72	64	Cough with dyspnoea or tachypnoea
	Bangladesh	4	58	82	Cough or difficult breathing or fast breathing
Malaria	Kenya	2	46	89	Diagnosis based on medical records, includes all malaria parasitaemia.
	Namibia	3	45	87	Fever and convulsion or loss of consciousness (all malaria parasitaemia)
	Namibia	3	72	85	Fever and convulsions or loss of consciousness (cerebral malaria only)
Malnutrition	Kenya	2	89	96	
	Namibia	3	73	76	
Accidents	Kenya	2	78	100	Accidents and major congenital problems
Sepsis	Kenya	2	61	81	Neonates
Neonatal tetanus	Philippines	1	94-100	-	
	Kenya	2	90	79	
	Bangladesh	4	97	98	
Measles	Philippines	1	98	90	Age ≥120 days, rash and fever ≥3 days
	Philippines	1	98	93	Age ≥120 days, fever ≥3 days, rash anywhere except extremities
	Philippines	1	83	99	Age ≥120 days, fever ≥3 days, rash anywhere except extremities, plus rash progression
	Kenya	2	90	96	Age ≥120 days, rash
	Namibia	3	71	85	Age ≥120 days, rash, fever ≥3 days
	Namibia	3	67	90	
Diarrhoea	Kenya	2	36	96	≥6 liquid stools per day
	Philippines	1	60	85	Frequent loose or liquid stools
	Philippines	1	78	79	≥6 liquid stools per day
	Namibia	3	56	90	Loose or liquid stools
	Namibia	3	89	61	≥6 liquid stools
	Bangladesh	4	77	97	

Study source:

1 Kalter HD, Gray RH, Black R. et al. Validation of post-mortem interviews to ascertain selected causes of death in children. *International Journal of Epidemiology*, 1990, 19:380-386.

2 Snow R, Armstrong J.R.M, Forster D. et al. Childhood deaths in Africa: Uses and limitations of verbal autopsies, *Lancet*, 1992, 340:351-355.

3 Mobley CC, Boerma JT, Tituss S et al. Validation study of verbal autopsy method for causes of childhood mortality in Namibia, *Journal of Tropical Pediatrics*, 1996, 42:365-369.

4 Osinski P. Personal Communication, 1992.

Source: Adapted from Measurement of overall and cause-specific mortality in infants and children: memorandum from a WHO/UNICEF meeting. *Bulletin of the World Health Organization*, 1994, 72(5):797-713.

2.6 *Sensitivity and specificity of verbal autopsies and their effect on cause-specific mortality estimates.*

Since verbal autopsies rely solely on information recalled by the next-of-kin for determining the cause of death, and are not based on clinical or laboratory evidence, they may be subject to relatively high misclassification errors. (Although, even diagnoses based on clinical and laboratory evidence may have substantial misclassification.) This can have a profound effect on the verbal autopsy estimate of the proportion of deaths due to a specific cause.[9]

The traditional way to validate a screening test is to measure sensitivity and specificity by comparing the screening test result to the true value from a so-called gold standard. This was a very important part of the validation studies carried out using the standard verbal autopsy questionnaire presented in this document. For some causes of death there are several different algorithms. Sensitivity and specificity for particular causes of death obviously vary with the algorithm used to establish cause of death. However, given the inverse relationship between sensitivity and specificity, it is not possible to select the algorithm with both the highest sensitivity and the highest specificity.

The accuracy of a verbal autopsy estimate of the cause-specific mortality fraction for different levels of sensitivity, specificity and cause-specific mortality pattern is presented in Table 2. It is measured by the difference between the verbal autopsy estimate of the cause-specific mortality fraction and the true cause-specific mortality fraction. For example, if the sensitivity and specificity of a verbal autopsy algorithm are both 70% for a fairly common cause of death (e.g. one which is responsible for 30% of deaths), the verbal autopsy would over-estimate the proportion of deaths due to that cause by approximately 12 percentage points (i.e. the verbal autopsy would classify 42% of the deaths as due to that particular cause, while in fact, only 30% of the deaths were really due to that cause). Even if the specificity were as high as 80% and sensitivity still 70%, the verbal autopsy would overestimate the proportion by 5 percentage points (35% vs 30%).

Table 2 can be helpful when evaluating the feasibility of using a verbal autopsy study in a particular setting, since it allows the analyst to observe how the accuracy of the verbal autopsy estimate varies with levels of sensitivity, specificity and cause-specific mortality fraction. It indicates that algorithms with only moderate levels of sensitivity and specificity are not suited for measuring rare causes of death, whereas they could provide approximate values for relatively common causes of death. Less common causes of death require very high rates of specificity (but can tolerate low levels of sensitivity). For example, a cause of death responsible for 5% of deaths, for which the specificity is 95%, would result in an over-estimate of only between 3 and 5 percentage points, for sensitivities ranging between 60% and 90%.

It would be possible to adjust for this misclassification if the sensitivity and specificity of the verbal autopsy algorithms were known.[10] The collaborating group has considered whether or not it might be advisable to correct for misclassification errors in

[9] Anker M. The effect of misclassification error on reported cause-specific mortality fractions from verbal autopsy. *International Journal of Epidemiology*, 1997, 26(5):1090-1096.

[10] For further information see Kalter H. The validation of interviews for estimating morbidity. *Health Policy and Planning*, 1992; 7(1): 30-39

future verbal autopsy studies using the validated questionnaire by using the sensitivities and specificities for specific algorithms resulting from the validation studies. One major problem with this approach is that it is not known if the sensitivities and specificities from a verbal autopsy validation study in a hospital setting are likely to be the same in a particular community setting. Even within the same cultural settings, one would expect some variation due to differences in the circumstances and characteristics of people who bring their children to the hospital and those who do not. One would also expect sensitivity and specificity to differ substantially across cultural and geographic settings. (In addition the disease mix and prevalence for each cause in the particular setting may change sensitivity and specificity). The collaborating group felt that while investigators using verbal autopsy should be fully aware of the measurement errors inherent to the method, we are not at the stage when one can correct for these errors by substituting known sensitivities and specificities from validation studies.

Misclassification not only affects estimates of levels of cause-specific mortality fractions but it also affects estimates of: (1) changes in cause-specific mortality fractions over time and (2) differences in cause-specific mortality fractions between two population groups. Maude and Ross[11] have shown that when specificity is less than perfect, the verbal autopsy method underestimates the difference between two cause-specific mortality estimates. Furthermore, this underestimation can be substantial, greatly reducing the power of studies designed to detect differences in cause-specific mortality rates over time or between two populations. The sample sizes required to overcome this problem can be very large.

[11] Maude GH & Ross DA. The effect of different sensitivity, specificity and cause-specific mortality fractions on the estimation of differences in cause-specific mortality rates in children from studies using verbal autopsies. *International Journal of Epidemiology*, 1997, 26(5):1097-1106.

Table 2. Differences between the verbal autopsy estimate and the true cause-specific mortality fraction, for different levels of specificity and sensitivity and for different cause-specific mortality fractions.

Sensitivity	True cause-specific mortality fraction	Specificity 0.60	0.70	0.80	0.85	0.90	0.95	0.99
0.60	.01	+.392	+.293	+.194	+.145	+.095	+.046	+.006
	.05	+.360	+.265	+.170	+.123	+.075	+.028	-.010
	.10	+.320	+.230	+.140	+.095	+.050	+.005	-.031
	.20	+.240	+.160	+.080	+.040	+.000	-.040	-.072
	.30	+.160	+.090	+.020	-.015	-.050	-.085	-.113
	.40	+.080	+.020	-.040	-.070	-.100	-.130	-.154
0.70	.01	+.393	+.294	+.195	+.146	+.096	+.047	+.007
	.05	+.365	+.270	+.175	+.128	+.080	+.033	-.005
	.10	+.330	+.240	+.150	+.105	+.060	+.015	-.021
	.20	+.260	+.180	+.100	+.060	+.020	-.020	-.052
	.30	+.190	+.120	+.050	+.015	-.020	-.055	-.083
	.40	+.120	+.060	.000	-.030	-.060	-.090	-.114
0.80	.01	+.394	+.295	+.196	+.147	+.097	+.048	+.008
	.05	+.370	+.275	+.180	+.133	+.085	+.038	-.001
	.10	+.340	+.255	+.160	+.115	+.070	+.025	-.011
	.20	+.280	+.200	+.120	+.080	+.040	+.000	-.032
	.30	+.220	+.150	+.080	+.045	+.010	-.025	-.053
	.40	+.160	+.100	+.040	+.010	-.020	-.050	-.074
0.90	.01	+.395	+.296	+.197	+.148	+.098	+.049	+.009
	.05	+.375	+.280	+.185	+.138	+.090	+.043	+.005
	.10	+.350	+.260	+.170	+.125	+.080	+.035	-.001
	.20	+.300	+.220	+.140	+.100	+.060	+.020	-.012
	.30	+.250	+.180	+.110	+.075	+.040	+.005	-.023
	.40	+.200	+.140	+.080	+.050	+.020	-.010	-.034
0.99	.01	+.396	+.297	+.198	+.148	+.099	+.049	+.010
	.05	+.380	+.285	+.190	+.142	+.095	+.047	+.009
	.10	+.359	+.269	+.179	+.134	+.089	+.044	+.008
	.20	+.318	+.238	+.158	+.118	+.078	+.038	+.006
	.30	+.277	+.207	+.137	+.102	+.067	+.032	+.004
	.40	+.236	+.176	+.116	+.086	+.056	+.026	+.002

Source: Anker M. The effect of misclassification error on reported cause-specific mortality fractions from verbal autopsy. *International Journal of Epidemiology*, 1997, 26(5): 1090-1096.

Chapter 3 Validation Studies

The three prospective validation studies of the verbal autopsy questionnaire discussed in this document were undertaken in Bangladesh, Nicaragua and Uganda.

In each study, validity was evaluated by administering the standard questionnaire to the mother or caregiver of infants and young children admitted to hospital, and comparing the results of the verbal autopsy to the hospital diagnosis.

Sites were selected to observe the performance of the verbal autopsy in settings with different disease patterns, cultural traditions, and overall mortality rates. It was thought that the prevalence of malaria and HIV might have an important influence on the accuracy of the questionnaire, since the symptomatology of these two diseases overlaps considerably with symptoms of other major causes of childhood deaths. One site (Uganda) had high endemic year-round transmission of malaria, while in Bangladesh and Nicaragua, very few hospitalizations were due to this cause. Similarly, Uganda has very high transmission of HIV infection when compared to the other two sites.

All three studies used the same basic protocol, so that their results could be compared across sites. The settings were either general paediatric hospital wards or maternity wards (for neonates). The study included severely ill children and young infants admitted to hospital, who were in danger of dying without hospitalization. Caregivers of these children were subsequently traced at home and interviewed using the verbal autopsy instrument, after the death or discharge of the child. The reason for following up all children with a verbal autopsy interview, rather than just those who died, was to have a study population as close as possible to that likely to be encountered in a field setting where the verbal autopsy interviews will inevitably be used.

3.1 *Hospital reference diagnoses*

A key feature of these validation studies was the importance given to the use of uniform, objective, and reproducible procedures for hospital examinations and hospital diagnoses of cause of severe illness or death. Standardized procedures and definitions were developed for the laboratory and clinical examinations on admission. The procedures consisted of definitions of terms used in the medical history of patients; a list of specific signs and symptoms to be investigated during the clinical examination on admission, combined with standard ways of recording them, as well as a general list of indications for ordering additional laboratory procedures and standard algorithms for diagnosing cause of death or severe illness. The combination of (a) stringent uniform procedures for medical and clinical examinations, and (b) algorithms for arriving at hospital medical diagnoses meant that the hospital reference diagnoses were comparable for all children in the studies. In addition, these procedures are detailed descriptions of the way in which the hospital diagnoses were arrived at, an important element for interpreting the validation studies themselves.

3.2 *Developing verbal autopsy algorithms*

Another important aspect of these studies was the development of expert verbal autopsy algorithms for attributing cause(s) of death or severe illness. Each algorithm consists of a predetermined set of rules for combining responses to specific questions in the verbal

autopsy interview. This results in either attributing a potential cause of death or severe illness to a child, or concluding that the death or severe illness of the child is not attributable to that cause.

The expert algorithms were developed before the validation studies were begun. The algorithms were therefore not based on data from the current study, but based on previous work and expert judgement. For most causes of death several expert verbal autopsy algorithms were proposed, in order to see which algorithms work best in particular settings, as well as which work best over all settings. These algorithms were then tested against a 'gold standard' consisting of strict hospital reference diagnoses. Results from the comparison of expert algorithms to hospital reference diagnoses are presented below.

Sometimes additional algorithms were developed during analysis, especially when the expert algorithms were not performing well. These are noted in the tables.

3.3 *Validation study results*

In this section, we present the results of the verbal autopsy validation studies. Tables 3 to 27 in Annex 1 present the sensitivity and specificity of different verbal autopsy algorithms in detecting relevant causes of death or severe illness using as the gold standard the hospital reference clinical diagnosis developed for these studies. Results are presented separately for neonates (less than 28 days old) and post-neonates (28 days old and above). Neonates were not included in the Ugandan study. Results for deaths and survivors of severe illness are combined; however, important differences between the results for deaths and survivors are indicated in the text.

The hospital reference diagnosis, which functions as the gold standard, is presented at the top of each table. For most causes, the reference diagnoses used in hospital were identical for all three sites. For the few exceptions, separate hospital diagnoses are presented for the sites concerned.

The number of cases included in the analysis of a particular cause of death depends on the number of cases with sufficient information to meet the reference standard criteria for that cause. These are presented in Tables 3-27 in Annex 1. N1 is the number of cases with a positive hospital reference diagnosis, and N2 is the number of cases with a negative hospital reference diagnosis. There are also some cases that had missing caregiver information for a specific verbal autopsy algorithm. These cases are excluded from the analysis for that algorithm. N3 is the number of cases with a positive hospital diagnosis for whom sufficient caregiver interview information is available to make the verbal autopsy diagnosis, while N4 is the number of cases with a negative hospital diagnosis and sufficient caregiver interview information. N3 and N4 are the denominators for calculations of sensitivity and specificity respectively. The total number of cases with a hospital reference diagnosis but missing information from the caregiver interview is equal to (N1+N2)-(N3+N4). The proportion of cases with missing caregiver information is (in addition to sensitivity and specificity) a criteria for judging the usefulness of the verbal autopsy algorithm.

When there were too few patients with the relevant hospital reference diagnosis from any site (taken as five or fewer here), these results were excluded from analysis, and not shown in the tables. Thus some tables exclude data for one or more sites.

3.3.1 *Diarrhoea and dysentery*

Four distinct categories of diarrhoea were considered, namely i) acute diarrhoea, ii) acute dysentery, iii) persistent diarrhoea or dysentery, and iv) any diarrhoea or dysentery. To be considered as acute, symptoms had to have lasted less than 14 days; persistent symptoms lasted 14 days or more. Evidence of blood in the stools was a requirement for dysentery, whereas evidence of no blood in the stools was required for diarrhoea. The term 'any diarrhoea or dysentery' refers to having any one of the diagnoses discussed above.

There were some important differences in the hospital reference diagnoses between the sites. For Uganda, the reference standard diagnoses were based on the caregiver's original report to the physician at the time of hospitalization, which included reports about the quality of the stools, whether or not there was blood in the stools, and the duration of symptoms. Only in the case of acute diarrhoea were any physician or medical notes considered, and these notes did not refer to the stools – but to observations of sunken eyes or reduced skin turgor. In Bangladesh and Nicaragua, the hospital reference diagnosis was based on medical notes on the quality of the stools and the presence and absence of blood and medically noted dehydration, in addition to the caregivers report on quality of stools and duration of symptoms.

Symptoms of diarrhoea are sometimes described in slightly different ways in the local language of different settings. This is true for other causes of death as well, but is of particular importance for diarrhoea and pneumonia. In the validation studies, questions on diarrhoea in the original English version asked about liquid or watery stools. However on translation into local languages, slightly different formulations emerged. The back-translations included loose or soft stools as well as liquid or watery stools (see Tables 3-8 in Annex 1). Local terms describing the stools, and the local term for diarrhoea are not necessarily identical, as their exact meanings vary with the local languages. An example of this occurs in the Bangladesh site (see Table 4) where there were important differences in sensitivity and specificity between local terms used for describing loose, liquid, soft or watery stools, and the local term for diarrhoea. One way to get around this problem is to construct an algorithm which combines questions about the quality of the stools with questions about whether the child had diarrhoea (using the local term for diarrhoea), and coding a positive response to any question as diarrhoea. This is a safer option than using either quality of stools or local terms for diarrhoea alone, because in a community study, which does not have hospital reference diagnoses, one does not know which particular formulation will work best in any particular community. In the current validation studies, in general, using the combined algorithm, rather than individual algorithms, resulted in at least as high or slightly higher sensitivity, with only slight losses of specificity.

3.3.1.1 *Acute diarrhoea*

Results for acute diarrhoea for neonates are shown in Table 3, and results for post-neonates are shown in Table 4. For neonates, only Nicaragua had enough cases for analysis. Sensitivity was low (52), but specificity was high (96). Although the hospital diagnosis and verbal autopsy algorithms for diarrhoea are the same for both age groups, neonates tend to have more frequent and softer stools than post-neonates. In Nicaragua, while the sensitivity was similar for both groups, specificity was higher for neonates than it was for post-neonates (96 and 83 respectively). The stools of breast-fed neonates tend to be softer and more frequent than those of post-neonates. This probably affects the mothers' responses to the

questions, as the mothers of breast-fed neonates would have softer and more frequent stools as a reference. Therefore, stools that these mothers consider to be particularly loose/soft and frequent, would be more likely to be diarrhoea, making specificity higher for neonates than for post-neonates.

For post-neonates, while sensitivity was relatively low for acute diarrhoea, specificity was moderate. The local term for diarrhoea worked very poorly in Bangladesh, illustrating why it is important to combine the local term for diarrhoea with a description of the stools of children suffering from diarrhoea.

3.3.1.2 *Acute dysentery*

Dysentery is rare in neonates, and in our sample there were too few neonates with acute dysentery to be analysed. There were also relatively few post-neonates with acute dysentery in our sample, 31 cases in all. The results indicate a high degree of specificity in all sites, while the sensitivity is quite low in Bangladesh and Nicaragua, and somewhat higher in Uganda (Table 5).

3.3.1.3 *Persistent diarrhoea or dysentery*

Neonates are unlikely to get dysentery, or to have diarrhoea for more than 14 days (partly because only the neonates who are at least 15 days old or more could possibly have had diarrhoea or dysentery for 15 days or more). In the three validation studies there were only two neonatal cases in Bangladesh - not enough to analyse.

For post-neonates, results for the three algorithms were very similar within sites (Table 6). They had low sensitivity in all three sites, with Bangladesh having extremely low sensitivity, and Nicaragua and Uganda having moderately low sensitivity. Specificity was relatively high in all three sites.

3.3.1.4 *Any diarrhoea or dysentery*

Any diarrhoea or dysentery is a combination of acute and persistent diarrhoea or dysentery. This combination does not require the caregiver to recall the duration of symptoms or whether or not there was blood in the stools, which are often not accurately remembered. Its disadvantage is that the researcher cannot distinguish between specific categories of diarrhoeal disease, which may have different causes and treatments.

The results for any diarrhoea or dysentery were relatively good, and were much better than the results for the three individual diagnoses. There was much higher sensitivity although somewhat lower specificity for any diarrhoea/dysentery than for the other more specific diagnoses. However, it is worth noting that among post-neonates in Uganda, the specificity of the verbal autopsy algorithms for any diarrhoea was poor. These results suggest that it may be advisable not to include blood in stools or duration of symptoms in verbal autopsy algorithms for diarrhoea.

For neonates, this suggestion makes particularly good sense. Dysentery and persistent diarrhoea are rare in neonates, and almost all diarrhoeal causes of death are likely to be acute diarrhoea. Therefore, distinctions made on the basis of duration or blood in the stools are likely to lead to added misclassification. This is seen clearly from the results of the validation

study in neonates in Nicaragua, Table 7 (the only site with enough cases of diarrhoea in neonates for analysis). Here the algorithms for any diarrhoea/dysentery had much higher sensitivity and only slightly less specificity than the algorithm for acute diarrhoea, even though all cases of diarrhoea in neonates were acute diarrhoea.

3.3.2 *Pneumonia*

One of the main reasons for validating the verbal autopsy in three different sites was to see how particular algorithms perform in settings with different disease mixes in the population, particularly for diseases with overlapping symptoms and signs. The symptoms and signs for pneumonia and malaria have considerable overlap. Since Bangladesh and Nicaragua have little or no malaria, and Uganda has very high rates of malaria, it was expected that the algorithm for pneumonia would be more specific in Bangladesh and Nicaragua than in Uganda.

For Uganda, only post-neonates were included, so that the comparison between Uganda and the other sites can only be made for post-neonates. Table 10 indicates that as expected the specificity was indeed lower in Uganda than in the other sites.

There are three verbal autopsy algorithms for pneumonia presented in Tables 9 and 10. The first algorithm was based on whether the caregiver indicated that the child had pneumonia using the local term for this condition. One problem with testing this algorithm is that medical cause of death/severe illness is normally communicated to the caregiver at the time of death or discharge from hospital. For pneumonia, the medical term is often identical to the local term. This influences caregivers subsequent responses and consequently, it is quite likely that the current validation studies over-estimate the sensitivities for the local term for pneumonia. Therefore, the validation study results for the algorithm that uses the local term for pneumonia should be interpreted cautiously. The same problem occurs with other causes of death.

In Bangladesh caregivers had difficulty responding to the questions about fast breathing and chest in-drawing, especially for neonates who did not have pneumonia. It may be that the absence of these signs is harder to recognize than their presence. In an analysis of neonates in the Bangladesh study, one of the authors (HK) has suggested that responses of 'don't know' should be coded as 'no'.[12] This would lower the sensitivity and raise the specificity of this algorithm in Bangladesh from 80 to 75 and from 59 to 70, respectively. In Nicaragua, there was a smaller proportion of missing cases for this expert algorithm, but here again, out of the 22 cases, 17 of the children did not have pneumonia. By coding 'don't know' as 'no', sensitivity would decrease from to 78 to 75 and specificity would increase from 30 from 47. In both sites the specificity of the algorithm would increase markedly, with only a small loss in sensitivity, when 'don't know' is coded as 'no'.

Overall, algorithm two had moderate to high sensitivity, with low specificity, while algorithm three had low to very low sensitively with moderate to high specificity. Because symptoms and signs of pneumonia are somewhat different in neonates than in post-neonates there were some differences between neonates and post-neonates. For example, cough is a less common sign of pneumonia in neonates than in post-neonates, while difficult breathing is less common in post-neonates who do not have pneumonia than in neonates without

[12] Kalter et al. Validation of caregiver interview to diagnose common causes of severe neonatal illness, *Paediatr. Perinat. Epidemiol.* 1999, Jan; 13(1): 99-113.

pneumonia. Both algorithms were more sensitive for post-neonates than for neonates, indicating that the positive signs of pneumonia are more easily recognized and recalled for post-neonates than for neonates, whereas the algorithm for cough and difficult breathing for more than two days was less specific for post-neonates than for neonates.

3.3.3 *Injuries*

There were sufficient numbers of injuries for analysis of post-neonates in Bangladesh and Nicaragua (Table 11). There were two algorithms for injuries, the first being whether caregivers reported injury to be the cause of hospitalization or death. This worked very well – although there were some misclassifications. The second algorithm required that the hospitalization or death occurred within 24 hours of the injury. This had low sensitivity for Nicaragua, and was not used in Bangladesh. This suggests that the 24 hour time limit from injury to death is too short.

Injuries were enquired about first in the verbal autopsy questionnaire, and if injury was cited as the cause of death or hospitalization, no further questions about the symptoms and signs present during the final illness were asked. This procedure was based on the assumption that there was little purpose in asking additional questions if injury had already been identified as the cause of death. However, the analysis indicated that there were some false-positives, for example, one mother in Nicaragua attributed the cause of an illness to an accident - swallowed dirty water - while the hospital reference cause of death was diarrhoea. In another case, a mother reported that the cause of death was due to the baby being dropped by the physician attending the birth, whereas the hospital reference diagnosis (confirmed on the death certificate) was pre-maturity and coma. There were also several cases where the mother attributed an illness to a fall ("fell out of hammock", "fell off the bed"), whereas it was diagnosed in hospital as something else such as pneumonia, meningitis, diarrhoea. It may be that mothers sometimes retrospectively attribute the cause of an illness to a prior event. This experience suggests that it may be wise to revise the questionnaire so that the report of an injury does not automatically end questionning about the final illness.

3.3.4 *Meningitis/encephalitis*

These two causes of death were combined in a single reference diagnosis, since it was not considered possible to distinguish between them on the basis of caregiver interviews (Tables 12 and 13). There were 8 cases of meningitis and 8 cases of encephalitis among neonates in Nicaragua. The expert verbal autopsy algorithm for neonates, namely 'fever and convulsions' had low sensitivity, and moderate specificity. It had much higher sensitivity, and about the same specificity for post-neonates. The low sensitivity of this algorithm for neonates is not surprising, because neonates often lack the focal signs of disease that older children have.

Considering post-neonates, fever had consistently high sensitivity and low specificity across sites whereas stiff neck and bulging fontanelle had consistently high specificity. The first two algorithms had somewhat higher sensitivity for deaths than for survivors, with similar specificity in Bangladesh. The algorithm combining fever and bulging fontanelle was the most consistent across sites, with moderately high sensitivity and specificity.

3.3.5 *Malnutrition/premature birth*

Malnutrition was divided into (i) severe or moderate malnutrition (weight-for-age Z-score less than -2) and (ii) severe malnutrition (weight for age Z-score less than -3). For neonates, low birth weight (LBW) and severe malnutrition were combined as one diagnosis on the assumption that a low weight-for-age Z-score measured several days after birth serves as a proxy for LBW. A low Z-score could also be due to poor postnatal nutrition but, given the short interval between birth and the time of measurement and that infants normally do not regain their birth weight until several days after birth, it is likely due primarily to low birth weight.[13] Premature birth was treated separately, as it is desirable to distinguish neonates who are small due to prematurity from those who are small due to poor intrauterine nutrition.

By and large the algorithms presented in Table 14 worked well for LBW/severe malnutrition in Bangladesh. The best algorithm seemed to be 'baby was very small or smaller than usual at birth' which had the highest sensitivity (89) and good specificity (85). Algorithms for prematurity had somewhat higher sensitivity and lower specificity (see Table 23). This is due to the fact that, while almost all (29/30) premature babies in Bangladesh were also diagnosed with LBW/severe malnutrition, 15 neonates had LBW/severe malnutrition alone. Thus, the comparison group included infants with a condition that is difficult to distinguish from prematurity. The overlap of reference standard prematurity and LBW/severe malnutrition may have been due to our inability to correct the weight-for-age Z-scores for gestational age.

For Nicaragua the situation was somewhat different. Premature babies without LBW/severe malnutrition were much more common in Nicaragua than in Bangladesh. In fact, in Nicaragua, of the 120 premature babies diagnosed, only 71 of them (60%), had low birth weight compared to 97% in Bangladesh. On the other hand, a somewhat larger proportion of LBW/severely malnourished babies were also born prematurely in Nicaragua than in Bangladesh. Twenty-two out of 93 LBW/severely malnourished babies in Nicaragua (24%), had LBW/severe malnutrition alone (for 13 of these, gestational age was not determined) compared to 33% in Bangladesh. This may be a reflection of the fact that in the general population, LBW occurs considerably less frequently in Nicaragua than it does in Bangladesh,[14] while the proportion of premature births in the general population varies less between the sites.

Surprisingly, the algorithm, 'baby was very small or smaller than usual at birth' did not work nearly as well in identifying LBW/severely malnourished neonates in Nicaragua (sensitivity/specificity 54/75) as in Bangladesh (sensitivity/specificity 89/85). One would have expected Nicaraguan mothers to have been more likely than Bangladeshi mothers to consider a low birth weight baby to have been very small or smaller than usual at birth – given that low birth weight is so much less common in Nicaragua. One possible explanation is that the question had not been understood properly in Nicaragua, and mothers were losing concentration at this point. In future questionnaires it would be useful to add an introductory

[13] The reference standard used for LBW/severe malnutrition was Z-score of less than –3. If the weight is taken at birth, this is equivalent to a birth weight of less than 2000 kg, well below the usual 2.5 kg LBW cutoff (which is equivalent to a Z-score of –1.9).

[14] For the year 1985, the World Development Report reported a LBW rate of 31% for Bangladesh compared to 15% in Nicaragua.

remark before question 8.9 such as 'Now I am going to ask you about the SIZE of the baby at birth. At the time of birth, how big was the baby?'

The algorithm that worked best in Nicaragua was 'pregnancy ended early' (sensitivity/specificity 85/75 respectively), underscoring the overlap between premature birth and LBW/severe malnutrition.

For post-neonates (Tables 15 and 16) the algorithms were more sensitive but slightly less specific for severe malnutrition than for severe and moderate malnutrition. This is in keeping with expectations, since the signs of malnutrition increase with severity. The patterns were similar across algorithms within countries, but in Bangladesh the algorithms were less sensitive and more specific than in Nicaragua and Uganda (where the specificity of all of the algorithms was too low to be considered useful).

Bangladesh has one of the highest rates of malnutrition among children in the world - far higher than in Uganda or Nicaragua. It is possible that under those circumstances, mothers notice signs of malnutrition less than in other sites, because it is so common. A similar result was found for diarrhoea, where mothers of neonates seemed to have noticed diarrhoea less, possibly because frequent soft stools occur more often in breast-fed neonates than in other children.

3.3.6 *Anaemia: post-neonates only*

There were two diagnoses for anaemia, namely (i) moderate or severe anaemia (Table 17) and (ii) severe anaemia (Table 18). Specificity was low for all verbal autopsy algorithms tested, although sensitivity was relatively high for severe anaemia. This was similar to the findings for malnutrition. The symptoms and signs used in the algorithms were not recalled very well by caregivers in Bangladesh, regardless of whether the children had anaemia or not. This is shown by the large number of cases where the verbal autopsy diagnosis is missing.

3.3.7 *Malaria: post-neonates only*

Malaria is an uncommon diagnosis in neonates and therefore was not considered for this age group. Because there is very little malaria at the sites in Bangladesh or Nicaragua, Uganda was the only site where malaria was considered for post-neonates (Table19). None of the expert verbal autopsy algorithms tested had high sensitivity (the highest was 41) and the specificity ranged from a low of 48 to a high of 93. Of two additional algorithms developed during data analysis, only one had both sensitivity and specificity greater than 50. This algorithm was 'convulsions' or 'stopped responding to voice' with sensitivity 55 and specificity 69. This underscores the difficulties of measuring malaria mortality using verbal autopsy.

3.3.8 *Measles: post-neonates only*

There were virtually no measles cases in the Bangladesh and Nicaragua studies and only six cases among post-neonates in Uganda (Table 20). In general, there was high sensitivity and specificity for measles for all three expert algorithms tested. The sensitivity of the algorithm that uses the local term for measles might be artificially inflated if the physician told the caregiver this diagnosis at the time of discharge or death.

3.3.9 *Bacteraemia/septicaemia with no known focus: neonates only*

There were stringent standards for the hospital reference diagnosis, requiring blood cultures. No cases were diagnosed in Uganda or Nicaragua, and there were only 8 cases among post-neonates in Bangladesh (Table 21). By far the best algorithm was the third algorithm 'fever for more than seven days, minus fast breathing and chest in-drawing and minus convulsions'.

3.3.10 *Birth asphyxia: neonates only*

Because Nicaragua was able to collect medical information only for neonatal deaths with birth asphyxia, there were only four cases with this reference diagnosis - not enough to analyse. Therefore, only data from Bangladesh is included in Table 22. For the two expert algorithms, sensitivity/specificity were 43/86 and 60/63. Some additional algorithms developed during the data analysis (Table 22) had higher levels of sensitivity and specificity and these are recommended for use.

3.3.11 *Premature birth: neonates only*

The algorithm on pregnancy ended early, had good levels of sensitivity and specificity for both sites (Table 23). In Nicaragua, only 250 out of a possible 358 neonates had a reference diagnosis for prematurity. This is probably due to the difficulty of measuring gestational age. There is considerable overlap of premature birth with low birth weight/severe malnutrition (see section 3.5.5).

3.3.12 *Congenital abnormality: neonates only*

There were insufficient cases for analysis in Bangladesh. The algorithm 'malformation present at birth' had sensitivity/specificity of 53/95 in Nicaragua (Table 24).

3.3.13 *Birth trauma: neonates only*

The sensitivity was low and specificity high for bruises or marks of injury on the body or head at birth for both Nicaragua and Bangladesh (Table 25). However, there were relatively few cases in either site.

3.3.14 *Local bacterial infection*

The algorithm tested had low sensitivity and high specificity (48 and 89 respectively) among neonates in Nicaragua - the only site with enough data to analyse (Table 26).

3.3.15 *Tetanus: neonates only*

Only Bangladesh had enough cases of neonatal tetanus for analysis (Table 27). Both the local term for tetanus and algorithm 3 had high sensitivity and specificity.

Chapter 4 Standard Verbal Autopsy Questionnaire

Chapter 4 and Annex 2 contain the material needed for carrying out a verbal autopsy study. This includes a brief description of the standard verbal autopsy questionnaire, the questionnaire itself, suggestions for adapting the questionnaire to the local setting, instructions to the interviewer and an explanation of terms used in the questionnaire.

4.1 *Description of questionnaire*

The description of the standard verbal autopsy questionnaire, which is reproduced in Annex 2, consists of nine sections. Each of these sections is briefly described below:

Section 1. Background information on child and household

Section 1 differs from other sections in the standard questionnaire in that it is filled in prior to visiting the household. It includes the household address (so that it can be located by the interviewer), and the deceased child's name, sex and designated identification number.

Section 2. Background information about the interview

Section 2 records background information on the interview, such as language of the interview (where necessary), interviewer's identification number, and dates of the interview and data entry. The table at the bottom of Section 2 is an easy-to-use form so that the interviewer can keep track of interview attempts, since it will often be necessary to revisit a household in order to interview the mother or caregiver of the deceased child.

Section 3. Information about caregiver/respondent

Section 3 collects background information about the caregiver/respondent, such as name, age, education and relationship to the child. Information on other persons present during the interviewer and the illness is also collected. Information on the caregiver/respondent serves two main purposes: it helps the supervisor or interviewer if either needs to revisit the respondent for further clarification, and it allows analysts the opportunity to relate cause of death and key characteristics of the caregiver. The questions on other persons present during the interview and illness provide useful information to assess the quality of the interview and the type of care given to the child.

Section 4. Information about the child

Section 4 collects crucial information about the child which allows calculation of the child's exact age at death and information about where the child died (and at which hospital or health facility if relevant).

Section 5. Open history question

Section 5 begins with an open-ended question which requests the respondent to describe the illness in her/his own words. This question provides the respondent with the chance to give a detailed rendition of the illness without any specific prompting from the interviewer except for asking whether there was anything else. From this unprompted verbal description of the illness and events surrounding it, the interviewer is asked to record the verbal history, and then check off all the diseases and symptoms mentioned by the respondent. This open-history question is followed up by questions enquiring about the length of time the child was ill before death (question 5.2) and the type of care sought outside of the home (question 5.3).

Section 6. Accident

Section 6 focuses on accidents such as injuries, accidents, poisoning, bites, burns and drowning. The main purpose of this short section is to determine if the child died from an injury or accident.

Section 7. Age determination and reconfirmation

Section 7 serves the very important purpose of determining whether the child was more or less than 28 days old when she or he died. Establishing this fact is essential for the standard verbal autopsy questionnaire, since there are different sets of questions for neonatal and post-neonatal deaths. For this reason, the interviewer is asked to calculate the child's age at death from answers to questions 4.1 and 4.2, and then ask the respondent to confirm whether this is correct. If there is an inconsistency, the interviewer and the respondent have to reconcile this and arrive at the correct age at death.

Section 8. Neonatal deaths

Sections 8 and 9 are the heart of the verbal autopsy questionnaire. They collect information on the signs and symptoms surrounding the child's illness and death in order to determine cause of death. Section 8 deals with neonatal deaths, and Section 9 deals with post-neonatal deaths.

Some aspects in sections 8 and 9 are similar. Interviewers are asked to demonstrate certain signs such as grunting, wheezing, stridor, noisy breathing and stiff neck in order to make sure that respondents understand the question being asked (see section 4.4 for explanations of these and other terms used in the standard verbal questionnaire). Also it is recommended that the local term is used whenever appropriate, such as for diarrhoea, pneumonia, tetanus and measles.

Some of the specific questions in sections 8 and 9 are the same. For example, the following questions are included in both sections: convulsions and fits (8.15, 9.1), unconsciousness (8.16, 9.12), bulging fontanelle (8.17, 9.17), skin rash (8.22, 9.18), fever (8.23, 9.1), loose or liquid stools (8.24, 9.2), diarrhoea (8.25, 9.3), cough (8.26, 9.4), difficulty in breathing (8.27, 9.5), fast breathing

(8.28, 9.6), indrawing of chest (8.30, 9.7), noisy breathing (8.31, 9.8), flaring of nostrils with breathing (8.32, 9.9), and pneumonia (8.33, 9.10).

Section 8 differs from section 9 to a substantial extent because of detailed questions surrounding the child's birth. Questions in section 8 include whether multiple or single birth (8.1); early or late/difficult pregnancy (8.2, 8.3); number of hours in labour, and when waters broke (8.5, 8.6); size, malformations and bruises on the body at birth (8.7-8.9); ability to breathe, suckle and cry at birth (8.10-8.14), redness or drainage from umbilical cord stump (8.20). Other topics addressed only in section 8 include: tetanus (8.18), yellow eyes (8.19), whether child ever stopped breathing (8.29), and some more specific questions about skin rashes and areas of red and hot skin (8.21, 8.22).

Section 9. Post-neonatal deaths

Questions asked only in section 9 include: loss of voice, ability to grasp, or ability to follow movement with eyes (9.13-9.15), stiff neck (9.16), becoming very thin (9.19), swollen legs and feet (9.20), skin flaking off in patches (9.21), hair changing colour to reddish/yellowish colour (9.22), kwashiorkor (9.23), marasmus (9.24), lack of blood or pallor (9.25), pale palms (9.26), and some more specific questions on skin rashes (9.18).

Section 10. Treatment and records

Section 10 collects various types of valuable information. This includes information from a possible death certificate to help establish cause of death (10.5 and 10.6); information from possible health records such child's weight (10.3) and medical notes (10.4); use of drugs during the child's illness (10.1); and whether the biological mother of the child has AIDS and/or has ever been tested for HIV.

The last two questions were left to the very end of the questionnaire because of the stigma attached to HIV/AIDS. (These were asked in Bangladesh and Uganda only.)

4.2 *General instructions to interviewers*

The following instructions apply to the entire questionnaire.

1. All questions should be read as they are written. This helps ensure that all respondents are asked questions in the same way. If the respondent does not understand the question, re-read it again more slowly. If she or he still does not understand, re-phrase the question, using terms that were discussed during your training.

2. In some questions, blank underlined spaces indicate that the name of the child should be read out in place of the blank space.

3. Some questions have several possible answers. The instructions indicate whether or not to read these pre-coded choices to the respondent, or whether the respondent's answers should be unprompted. Instructions also indicate whether or not multiple responses/answers are allowed to a question.

4. Most questions record the person's response by ticking the box next to the response. For example, the possible answers to a question may be "1. Yes " and "2. No ". The box next to "1. Yes" or "2. No" should be ticked.

5. Dates should be reported in the following way in the spaces provided:
dd is the day of the month (if less than "10", then the first digit is "0");
mm is the month of the year (January=01, February=02, March=03, April=04, May=05, June=06, July=07, August=08, September=09, October=10, November=11,December=12); and
yy is the last two digits of the year (drop the "20" from "20__").

6. Where an answer requires more specific information, as in "Other health facility (specify _____)" or "Other male (specify _____)", the information given by the respondent (for example, "health centre" or "brother") should be recorded in the space provided.

4.3 *Adapting the questionnaire to the local setting (translation, determining appropriate local terms, back-translation, and pre-testing)*

When adapting a verbal autopsy questionnaire to a local setting, it is important to have prior knowledge about the community, the health care system, and common diseases and causes of death, and to use common sense in applying the method. For example, if a disease or cause of death, such as malaria, is known not to be present in a particular setting, it does not make sense to use the verbal autopsy algorithms to estimate the prevalence of malaria. Even in an area with no malaria whatsoever, the verbal autopsy algorithms is likely to result in some false-positives which could be misleading.

The questionnaire should be translated into the local language by someone who is fluent in both English and the local language, and who is familiar with local lay medical terminology. This may be a physician with extensive experience working with poor persons in the community, or another person familiar with health terms. It is important to capture the intent of each question, rather than the exact words. If possible, a local anthropologist or demographer should check the translation for accuracy of intended meaning and suggest needed corrections. They may check parts of the questionnaire by presenting it to local mothers. A third person, unfamiliar with the original questionnaire and fluent in both English and the local language, should back translate the questionnaire. The back translation should be compared to the original questionnaire to make certain that the intent of each question reflects the original medical meaning.

Alternative local terms for medical conditions as well as symptoms and signs of illness should be considered both during the translation phase and also during interviewer training. It is very important that attention is paid to the language of sickness that people normally use in the community, which may be very different from the clinical language of pathologies. The generic questionnaire reproduced in this document indicates appropriate locations for interviewers to insert possible local terms or for those local terms to be printed

directly on the questionnaire. It is an important part of training to discuss alternative expressions to use if the respondent does not initially understand a question.

Some terms in the interview such as stridor, grunting and wheezing are demonstrated by the interviewer. These should be practised during the training sessions. Once the interviewers, supervisor and trainer agree on the final first draft questionnaire, the interviewers should pre-test it by interviewing several caregivers of severely ill or recently deceased children. This can be done in hospital or at nearby homes. Pre-testing affords the interviewers an opportunity to practice, as well as serving as testing out the questionnaire. Any problems must be resolved before taking the final questionnaire to the field.

4.4 *Explanations of terms used in the standard verbal autopsy questionnaire*

These explanations are particularly useful for interviewer training and field work. Before beginning the field work, interviewers should be thoroughly familiar with these terms and should be able to explain them to respondents in a simple way.

Breathing (difficult) – The child is working harder than normal to breathe.

Breathing (rapid) – The child is breathing faster than normal.

Birth (multiple) – Two or more infants are born from the same pregnancy, whether or not the babies are born alive.

Bulging fontanelle – "Fontanelle" is the soft spot toward the front of an infant's head. "Bulging" means that it was pushed out and tense when the infant was in a sitting position.

Chest indrawing – "Indrawing" means that the lower part of the chest moved in (collapsed) when the child took a breath.

Coma – The child is unaware of what is happening around him/her, and is unable to respond to any stimuli.

Complicated delivery – A difficult birth. The mother or infant experienced a problem such as infection, too much bleeding, trouble breathing, or an injury.

Convulsion – A fit; uncontrollable jerking and stiffening of the arms and legs, perhaps with biting of the tongue and loss of urine and faeces.

Diarrhoea – Abnormally frequent liquid or watery stool.

Fever – The child feels hot to the touch, or the temperature is abnormally high as measured with a thermometer.

Fit – See convulsion.

Nasal flaring – Nasal flaring means that the nostrils opened wide when the infant took a breath.

Generalized convulsion or fit – "Generalized" means all over the body.

Grunting – This is a short, low-pitched sound that occurs at the start of breathing out. It indicates the child is trying to open the lungs further.

Injury – The child is hurt by something outside the body, such as a motor vehicle accident, fall, drowning, poisoning, burn, bite sting by venomous animal, violence or other injury including accidental and intentional injuries.

Jaundice – Yellowing of the skin or the whites of the eyes.

Kwashiorkor – A nutritional disorder with swelling from fluid in the hands or lower legs.

Labour (beginning of labour) – Labour begins when there are regular contractions no more than 10 minutes apart.

Lack of blood or pallor – "Lack of blood" or "pallor" means that the child did not have as much colour as usual.

Malformation – One or more body parts are not shaped normally.

Malaria – A disease passed by mosquitos that causes a high fever.

Marasmus – A nutritional disorder with a very thin body and limbs.

Measles – A disease of young children with a rash all over the body and fever.

Pale palms – "Pale palms" means that the palms of the child's hands did not have as much colour as usual.

Pneumonia – A lung infection that may cause a cough and difficult or fast breathing.

Rash – Any abnormality of the skin that is not a cut or bruise. Rashes are caused by many illnesses.

Stiff neck – The child holds the neck back stiffly and resists moving it.

Stridor – This is a high-pitched whistling sound that occurs when the child breathes in. It indicates an air blockage.

Swollen legs or feet – Swollen legs or feet means that there was extra fluid in the lower legs or feet.

Tetanus – A disease with convulsions and muscle spasms. Neonatal tetanus occurs in newborns and also includes loss of ability to suck or cry.

Unresponsive, unconscious – "Unresponsive/unconscious" means the infant was unable to respond to any stimuli such as light, sounds or touch.

Wheezing – This is a high-pitched sound that occurs most often when the child is having trouble breathing out.

White nails – "White nails" means that the nails of the hands did not have as much colour as usual.

Yellow eyes – "Yellow eyes" means that the whites of the eyes were yellowish in colour.

Annex 1

Tables of sensitivity and specificity of verbal autopsy algorithms for Bangladesh, Nicaragua and Uganda validation studies

Table 3 Acute diarrhoea – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Caregiver's history of liquid, watery, loose or soft stools for <14 days
and
either medically noted liquid/semi-liquid or watery stools or medically noted dehydration
and
no medically noted blood in stools.

Verbal autopsy algorithm	Nicaragua	
	N1=23	N2=314
	Sensitivity (N3)	Specificity (N4)
Acute diarrhoea		
1. Frequent liquid/watery/loose or soft stools <14 days and no blood in stools	52% (21)	96% (270)
2. Local term for diarrhoea <14 days and no blood in stools	57% (21)	95% (266)
3. Frequent liquid/watery/or loose or soft stools or local term for diarrhoea for <14 days and no blood in stools	57% (21)	94% (270)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 4 Acute diarrhoea – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Nicaragua and Bangladesh**:**

Caregiver's history of liquid, watery, loose, or soft stools for <14 days
and
either medically noted liquid/semi-liquid or watery stools or medically noted dehydration
and
no medically noted blood in stools.

Uganda:

Caregiver's history of liquid, watery, loose or soft stools for <14 days
and
physician's observation of sunken eyes or reduced skin turgor
and
no caregiver report of blood in stools.

	Bangladesh		Nicaragua		Uganda	
	N1=77	N2=316	N1=283	N2=464	N1=19	N2=250
Verbal autopsy algorithm	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**
Acute diarrhoea						
1. Frequent liquid/ watery/loose or soft stools <14 days and no blood in stools	47% (76)	78% (314)	58% (265)	83% (449)	53% (19)	77% (247)
2. Local term for diarrhoea <14 days and no blood in stools	29% (72)	89% (302)	58% (265)	84% (449)	63% (19)	76% (249)
3. Frequent liquid/watery/ loose or soft stools or local term for diarrhoea for <14 days and no blood in stools	49% (76)	77% (306)	58% (265)	84% (449)	63% (19)	75% (247)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 5 Acute dysentery - post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Bangladesh and Nicaragua:
Caregiver's history of liquid, watery or loose or soft stools or diarrhoea for <14 days plus medically noted liquid or semi-liquid or watery stools plus medically noted blood in the stools.

Uganda: Caregiver's report of frequent watery, loose, liquid or soft stools or diarrhoea < 14 days plus caregiver's report of blood in the stools.

	Bangladesh		**Nicaragua**		**Uganda**	
	N1=12	**N2=381**	**N1=13**	**N2=733**	**N1=6**	**N2=263**
Verbal autopsy algorithm	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N2)**	**Sensitivity (N3)**	**Specificity (N4)**
Acute dysentery						
1. Frequent liquid/watery/loose or soft stools plus blood in the stools plus duration <14 days	25% (12)	97% (378)	27% (11)	91% (702)	67% (6)	93% (261)
2. Diarrhoea (local term) plus blood in the stools plus duration <14 days	18% (11)	98% (363)	36% (11)	91% (703)	67% (6)	93% (263)
3. Frequent liquid/watery/loose or soft stools or local term for diarrhoea plus blood in the stools plus duration <14 days	25% (12)	97% (370)	36% (11)	91% (703)	67% (6)	93% (261)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 6 Persistent diarrhoea or dysentery – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Nicaragua and Bangladesh:
Caregiver's history of liquid, watery, loose or soft stools or diarrhoea for ≥ 14 days
and either medically noted liquid or semi-liquid or watery stools
or medically noted blood in the stools.

Uganda:
Caregiver's report of frequent loose, liquid, or soft stools or diarrhoea ≥ 14 days.

Verbal autopsy algorithm	Bangladesh		Nicaragua		Uganda	
	N1=26	N2=367	N1=27	N2=743	N1=22	N2=247
	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)
Persistent diarrhoea or Dysentery						
1. Frequent liquid/watery/loose or soft stools plus duration ≥ 14 days	19% (26)	95% (366)	46% (26)	94% (716)	59% (22)	86% (244)
2. Local term for diarrhoea plus duration ≥ 14 days	16% (25)	96% (350)	46% (26)	94% (718)	59% (22)	86% (246)
3. Frequent liquid/watery/loose or soft stools or local term for diarrhoea plus duration ≥14 days	19% (26)	95% (358)	46% (26)	94% (718)	59% (22)	86% (244)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 7 Any diarrhoea or dysentery - neonates
(Deaths and survivors combined)

Hospital Reference Diagnosis:

Caregiver's history of liquid, watery, loose or soft stools and either medically noted liquid/semi-liquid stools or medically noted dehydration.

Verbal autopsy algorithm	Nicaragua	
	N1=28	N2=309
	Sensitivity (N3)	Specificity (N4)
Any diarrhoea or dysentery		
1. Frequent liquid/ watery/loose/or soft stools	91% (22)	92% (273)
2. Local term for diarrhoea	91% (23)	93% (272)
3. Frequent liquid/watery/loose/or soft stools or local term for diarrhoea	91% (23)	91% (276)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 8 Any diarrhoea or dysentery – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Caregiver's history of liquid, watery, loose or soft stools and either medically noted liquid/semi-liquid stools or medically noted dehydration.

	Bangladesh		**Nicaragua**		**Uganda**	
	N1=115	**N2=278**	**N1=351**	**N2=430**	**N1=47**	**N2=224**
Verbal autopsy algorithm	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**
Any diarrhoea or dysentery						
1. Frequent liquid/ watery/ loose/or soft stools	72% (115)	78% (278)	85% (340)	77% (428)	91% (47)	57% (224)
2. Local term for diarrhoea	52% (108)	90% (267)	88% (340)	78% (430)	96% (47)	57% (224)
3. Frequent liquid/watery/loose/or soft stools or local term for diarrhoea	73% (115)	76% (270)	88% (340)	76% (430)	96% (47)	54% (224)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 9 Pneumonia – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Bangladesh:
Chest X-ray positive for pneumonia or (physician diagnosis of pneumonia plus crepitations or lower chest wall indrawing).

Nicaragua:
Chest X-ray positive for pneumonia or (physician diagnosis of pneumonia plus crepitations or sub-costal retractions).

	Bangladesh		**Nicaragua**	
	N1=32	**N2=86**	**N1=111**	**N2=122**
Verbal autopsy algorithm	Sensitivity **(N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**
Pneumonia				
1. Local term for pneumonia	74% (27)	87% (52)	58% (104)	82% (95)
2. Cough or difficult breathing and fast breathing or chest indrawing	80% (30)	59% (64)	78% (107)	30% (105)
3. Cough >2 days and difficult breathing > 2 days*	41% (32)	93% (80)	16% (111)	94% (121)

***** This algorithm was developed during data analysis.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 10 Pneumonia – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Uganda and Nicaragua:
Chest X-ray positive for pneumonia or (physician diagnosis of pneumonia plus crepitations or sub-costal retractions).

Bangladesh:
Chest X-ray positive for pneumonia or (physician diagnosis of pneumonia plus crepitations or lower chest wall indrawing).

	Bangladesh		**Nicaragua**		**Uganda**	
	N1=245	**N2=148**	**N1=439**	**N2=130**	**N1=152**	**N2=118**
Verbal autopsy algorithm	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**
Pneumonia						
1. Local term for pneumonia	75% (213)	83% (126)	76% (431)	66% (124)	74% (150)	40% (114)
2. Cough or difficult breathing and fast breathing or chest indrawing*	86% (235)	68% (136)	88% (439)	40% (130)	77% (149)	37% (117)
3. Cough > 2 days and difficult breathing > 2 days**	64% (244)	84% (146)	43% (439)	76% (130)	51% (152)	68% (118)

* This algorithm had somewhat lower sensitivity and higher specificity for deaths (78/83) than for survivors (86/65) in Bangladesh.

** This algorithm was developed during the data analysis.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 11 Injury – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Death or hospitalization due to motor vehicle accident, fall, drowning, poisoning, burn, bite, sting by venomous animal, violence or other injury.

	Bangladesh		Nicaragua	
	N1=12	N2=381	N1=30	N2=745
Verbal autopsy algorithm	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**
Injury				
1. Death due to motor vehicle accident, fall, drowning, poisoning, burn, bite, sting by venomous animal, violence or other injury	100% (12)	98% (381)	83% (30)	99% (745)
2. Death within 24 hours due to motor vehicle accident, fall, drowning, poisoning, burn, bite, sting by venomous animal, violence or other injury			57% (30)	100% (745)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 12 Meningitis/encephalitis – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Meningitis
Positive lumbar puncture defined as any of the following:

- culture or bacteria seen on Gram stain
- >=100 leukocytes/mm^2 and CSF with > 80% PMNs
- positive latex agglutination test

Encephalitis:
Positive lumbar puncture defined as all of the following:

- >10 leukocytes/mm^3 and > 50% lymphocytes
- no bacteria seen on Gram's stain of CSF
- no bacteria seen on CSF culture (if performed)

Verbal autopsy algorithm	Nicaragua	
	N1=16	N2=104
	Sensitivity (N3)	Specificity (N4)
Meningitis/encephalitis		
1. Fever (hot body) and convulsions	43% (14)	80% (92)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 13 Meningitis/encephalitis – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Meningitis:
Postive lumbar puncture defined as any of the following:
- culture or bacteria seen on Gram stain
- >=100 leukocytes/mm^2 and CSF with > 80% PMNs
- positive latex agglutination test

Encephelitis:
Positive lumbar puncture defined as all of the following:
- > 10 or more leukocytes/mm^3 and > 50% lymphocytes
- no bacteria seen on Gram's stain of CSF
- no bacteria seen on CSF culture (if performed)

	Bangladesh		Nicaragua	
	N1=35	N2=355	N1=20	N2=215
Verbal autopsy algorithm	**Sensitivity (N3)**	**Specificity (N4)**	**Sensitivity (N3)**	**Specificity (N4)**
Meningitis/encephalitis				
1. Fever (hot body) and convulsions and one or more of the following: - stopped being able to grasp - stopped being able to follow movements with eyes - stopped being able to respond to a voice (all > 12 hours before death)	63% (27)	92% (345)	25% (20)	91% (214)
2. Fever (hot body) and stiff neck or bulging fontanelle and one or more of the following: - stopped being able to grasp - stopped being able to follow movements with eyes - stopped being able to respond to a voice (all > 12 hours before death)	58% (26)	92% (313)	20% (20)	94% (214)
3. Fever (hot body) and stiff neck or bulging fontanelle	81% (31)	85% (302)	75% (20)	79% (214)
4. Fever (hot body) and convulsions	79% (34)	87% (353)	75% (20)	61% (214)
5. Stiff neck or bulging fontanelle and either fever or convulsions or unconscious for a long time or stopped being able to grasp, respond to a voice or follow movement with eyes*	87% (31)	83% (296)	71% (17)	80% (173)

* This algorithm was developed during the data analysis.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.
N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview
N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis
N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 14 Low birth weight/severe malnutrition - neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Weight-for-age Z score < -3.

Verbal autopsy algorithm	Bangladesh		Nicaragua	
	N1=46	N2=72	N1=93	N2=241
	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)
Low birth weight /severe malnutrition				
1. Pregnancy ended early or baby was very small at birth	82% (45)	80% (71)	86% (91)	68% (240)
2. Baby was very small at birth*	58% (45)	94% (71)	43% (88)	79% (230)
3. Baby was very small or smaller than usual at birth*	89% (45)	85% (71)	54% (91)	75% (240)
4. Pregnancy ended early*	78% (45)	83% (71)	85% (89)	75% (232)
5. Pregnancy ended early and baby was very small or smaller than usual at birth*	76% (45)	96% (71)	49% (91)	86% (240)

* These algorithms were developed during the data analysis.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 15 Severe or moderate malnutrition - post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Weight-for-age Z score < -2.

Verbal autopsy algorithm	Bangladesh		Nicaragua		Uganda	
	N1=234	N2=159	N1=298	N2=469	N1=85	N2=98
	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)
Severe or moderate malnutrition						
1. Very thin during the illness or had swollen legs or feet	49% (233)	77% (155)	86% (298)	32% (469)	82% (85)	48% (98)
2. Very thin during illness or local term for kwashiorkor*	52% (233)	77% (156)	84% (296)	37% (467)	80% (84)	54% (98)
3. Very thin during the illness or hair changed colour or skin flaked off in patches or had kwashiorkor during the prior month*	62% (214)	62% (134)	86% (298)	31% (469)	85% (85)	43% (98)

* In Nicaragua there was no identified local term for kwashiorkor.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 16 Severe malnutrition – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Weight-for-age Z score <-3

Verbal autopsy algorithm	Bangladesh		Nicaragua		Uganda	
	N1=145	N2=248	N1=152	N2=615	N1=38	N2=145
	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)
Severe malnutrition						
1. Very thin during illness or had swollen legs or feet	57% (145)	73% (243)	89% (152)	29% (615)	92% (38)	41% (145)
2. Very thin during illness or kwashiorkor*	63% (145)	73% (244)	88% (152)	33% (611)	92% (38)	47% (144)
3. Very thin during illness or swollen legs or feet or hair changed colour or skin flaked off in patches or had kwashiorkor (local term) during the prior month*	68% (139)	58% (209)	89% (152)	28% (615)	95% (38)	37% (145)
4. Very thin during illness or local term for "marasmus" or "kwashiorkor"*	52% (145)	75% (240)	-	-	95% (38)	44% (144)

* In Nicaragua there was no identified local term for kwashiorkor.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 17 Severe or moderate anaemia - post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Haematocrit < 24% or haemoglobin < 8 g/dl.

Verbal autopsy algorithm	Bangladesh		Nicaragua		Uganda	
	N1=117	N2=180	N1=92	N2=571	N1=58	N2=143
	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)
Severe or moderate anaemia						
1. Pale palms or white nails	71% (76)	48% (120)	75% (91)	33% (557)	76% (58)	45% (139)
2. Lack of blood/pallor and either pale palms or white nails	58% (89)	57% (143)	72% (90)	38% (552)	74% (58)	47% (139)
3. Informant mentioned anaemia in open question			16% (92)	96% (571)		

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 18 Severe anaemia – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Haemoglobin < 5 g/dl or haematocrit < 15%.

Verbal autopsy algorithm	Bangladesh		Nicaragua		Uganda	
	N1=28	N2=269	N1=12	N2=651	N1=10	N2=191
	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)
Severe anaemia						
1. Pale palms or white nails	90% (21)	45% (175)	75% (12)	32% (636)	90% (10)	40% (187)
2. Lack of blood or pallor and either pale palms or white nails	86% (22)	55% (210)	67% (12)	37% (630)	80% (10)	42% (187)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 19 Malaria – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Positive thick blood smear (≥ 1 parasite/hpf) and (caregiver report of fever in the past 24 hours or measured fever or hypothermia) and (altered consciousness without meningitis or laboured breathing without pneumonia or haematocrit <18%).

Verbal autopsy algorithm	Uganda	
	N1=29	N2=203
	Sensitivity (N3)	Specificity (N4)
Malaria		
1. Fever and at least two of the following: • convulsions • stopped following with eyes • difficult breathing • pallor and no stiff neck and no bulging fontanelle and no measles	34% (29)	65% (192)
2. Fever and convulsions and no stiff neck and no bulging fontanelle and no measles	24% (29)	93% (200)
3. Fever and (convulsions or stopped responding to a voice or stopped grasping or stopped following with eyes or unresponsive or difficult breathing) and no stiff neck and no bulging fontanelle and no measles	41% (29)	48% (194)
4.Convulsions or stopped responding to voice*	55% (29)	69% (200)
5.Convulsions or stopped responding to voice and fever and no stiff neck*	45% (29)	77% (197)

* These algorithms were developed during the data analysis.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 20 Measles – post-neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Presence of generalized rash and physician's diagnosis of measles.

Verbal autopsy algorithm	Uganda	
	N1=6	N2=265
	Sensitivity (N3)	Specificity (N4)
Measles		
1. Local term for measles	100% (5)	88% (244)
2. Age ≥ 120 days and fever and rash on face	83% (6)	85% (265)
3. Age ≥ 120 days and fever ≥ 3 days and rash ≥ 3 days and rash on face	83% (6)	86% (265)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 21 Bacteraemia/septicaemia with no known focus post-neonates (*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Rectal temperature > 38°C plus positive blood culture plus either (for septicaemia) non-consolable irritability, abnormally sleepy or difficult to wake, mottled and cool extremities, or pale and shocky on examination (minus all these signs for bacteraemia) minus reference standard pneumonia, bacterial meningitis, acute or persistent diarrhoea or dysentery, and local bacterial infection.

Verbal autopsy algorithm	Bangladesh	
	N1=8	N2=385
	Sensitivity (N3)	Specificity (N4)
Bacteraemia/septicaemia with no known focus		
1. Fever and (either stopped being able to grasp or respond to a voice or follow movements with eyes) minus fast breathing and indrawing and minus convulsions	29% (7)	93% (353)
2. Fever and either (stopped being able to grasp or respond to a voice or follow movements with eyes) minus (cough > 1 day and chest indrawing > 1 day) minus convulsions	14% (7)	93% (368)
3. Fever > 7 days minus (fast breathing and chest indrawing) minus convulsions*	75% (8)	91% (376)

* This algorithms was developed during the data analysis.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 22 Birth asphyxia – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Medical history of birth asphyxia (no spontaneous breathing at birth or 20 minute APGAR score < 4) plus either lethargy, coma, hypotonia or seizures plus rectal temperature always between 36°C and 38°C.

Verbal autopsy algorithm	Bangladesh	
	N1=19	N2=86
	Sensitivity (N3)	Specificity (N4)
Birth asphyxia		
1. No fever and not able to breath after birth and either convulsions/spasms or not able to suckle normally after birth or not able to cry after birth	43% (14)	86% (76)
2. No fever and either convulsions/spasms or not able to suckle normally after birth or not able to cry after birth	60% (15)	63% (71)
3. Not able to cry after birth and either not able to breathe after birth or not able to suckle normally after birth)*	73% (15)	72% (75)
4. Not able to cry after birth and either (convulsions/spasms or not able to suckle normally after birth)*	87% (15)	69% (76)

* These algorithms were developed during the data analysis.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 23 Premature birth – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Medical history or physician diagnosis of birth at less than 37 weeks of gestation.

Verbal autopsy algorithm	Bangladesh		Nicaragua	
	N1=30	N2=65	N1=120	N2=130
	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)
Premature birth				
1. Pregnancy ended early or baby was very small at birth	90% (30)	72% (65)	81% (118)	78% (129)
2. Baby was very small a birth*	67% (30)	85% (65)	42% (114)	89% (121)
3. Baby was very small or smaller than usual at birth*	93% (30)	68% (65)	51% (118)	84% (129)
4. Pregnancy ended early*	90% (30)	78% (65)	79% (115)	85% (125)
5. Pregnancy ended early and baby was very small or smaller than usual at birth*	87% (30)	85% (65)	46% (118)	95% (129)

* These algorithms was developed during the data analysis

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 24 Congenital abnormality – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Medically noted congenital abnormality.

Verbal autopsy algorithm	Nicaragua	
	N1=43	N2=293
	Sensitivity (N3)	Specificity (N4)
Congenital abnormality		
1. Malformation present at birth	53% (43)	95% (291)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 25 Birth trauma – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Physician final diagnosis of birth trauma.

Verbal autopsy algorithm	Bangladesh		Nicaragua	
	N1=8	N2=104	N1=13	N2=326
	Sensitivity (N3)	Specificity (N4)	Sensitivity (N3)	Specificity (N4)
Birth trauma				
1. Bruises or marks of injury on the body or head at birth	50% (8)	94% (104)	40% (10)	85% (275)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 26 Local bacterial infection – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Medical record of red or purulent umbilicus or skin pustules.

Verbal autopsy algorithm	Nicaragua	
	N1=25	N2=312
	Sensitivity (N3)	Specificity (N4)
Local bacterial infection Child's belly-button went red or pus or discharge from belly-button or parts of child's skin became inflamed, red and hot or skin rash with bumps containing pus and fever for one day or more	48% (25)	89% (233)

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Table 27 Tetanus – neonates
(*Deaths and survivors combined*)

Hospital Reference Diagnosis:

Physician diagnosis of neonatal tetanus and age >2 days.

Verbal autopsy algorithm	Bangladesh	
	N1=20	N2=98
	Sensitivity (N3)	Specificity (N4)
Tetanus		
1.Tetanus (local term)	88% (17)	95% (75)
2.Age 3-27 days and convulsions or spasms and able to suckle and cry normally after birth and stopped suckling or crying	67% (18)	91% (94)
3. Age 3-27 days and convulsions or spasms and able to suckle or cry normally after birth and stopped suckling or crying.*	83% (18)	89% (95)

* This algorithm was developed during the data analysis.

Notes:

N1 = Number of cases with a positive hospital diagnosis, and a caregiver interview.

N2 = Number of cases with a negative hospital diagnosis, and a caregiver interview.

N3 = Number of cases with a positive hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

N4 = Number of cases with a negative hospital diagnosis for whom sufficient caregiver interview data are available to make a verbal autopsy diagnosis.

Annex 2

Standard Verbal Autopsy Questionnaire

Instructions to interviewer: Introduce yourself and explain the purpose of your visit. Ask to speak to the mother or to another adult caretaker who was present during the illness that lead to death. If this is not possible, arrange a time to revisit the household when the mother or caretaker will be home.

Section 1: Background information on child and household
(*To be filled in before interview*)

1.1 Address of household _____
_____
_____
_____
_____
_____
_____

1.2 Name of child _____

1.3 Identification number of child/household _____ G G G G G

1.4 Sex of child: 1. Male G 2. Female G

Section 2: Background information about the interview

2.1 Language of interview: _____

2.2 Interviewer identification number: _____

	day/month/year
Date of first interview attempt	
Date and time arranged for second interview attempt	
Date and time arranged for third interview attempt	
Date of interview	
Date form checked by supervisor	
Date entered in computer	

Section 3: Information about caretaker/respondent

3.1 What is the name of the main respondent? _____

3.2 What is the relationship of main respondent to deceased child? (*tick relevant box*)

1. Mother **G**
2. Father **G**
3. Grandmother **G**
4. Grandfather **G**
5. Aunt **G**
6. Uncle **G**
7. Other male (specify) _____ **G**
8. Other female (specify)_____ **G**

3.3 What is the age of main respondent (in years) __ __

3.4 How many years of school did the main respondent complete? __ __

3.5 Were other people present at the interview?

1. Yes **G** 2. No **G**
(*If "No", go to question 3.5.3*)

3.5.1 Of those present at the interview, which were present at the illness that led to death/hospitalization? (*tick all relevant boxes*)

		Present at interview	Present during illness
1.	Mother	**G**	**G**
2.	Father	**G**	**G**
3.	Grandmother	**G**	**G**
4.	Grandfather	**G**	**G**
5.	Aunt	**G**	**G**
6.	Uncle	**G**	**G**
7.	Other male (specify _____)	**G**	**G**
8.	Other female (specify _____)	**G**	**G**

3.5.2 Total number present at interview (excluding interviewer) __ __

3.5.3 If mother is not present at the interview, is the mother still alive? Yes **G** No **G**

Section 4: Information about the child

4.1 Date of birth of child: ___/___/___
dd mm yy

4.2 What was the date of _____'s death? ___/___/___
dd mm yy

4.3 Where did _____ die? (*tick relevant box*)

1. Hospital **G**
2. Other health facility **G**
3. On route to hospital or health facility **G**
4. Home **G**
5. Other (specify _____) **G**

4.3.3 For deaths at hospital or health facility, record facility name and address:

_____
_____
_____
_____

Section 5: Open history question

5.1 Could you tell me about _____'s illness that led to death?

Prompt: Was there anything else?

Instructions to interviewer - Allow the respondent to tell you about the illness in his or her own words. Do not prompt except for asking whether there was anything else after the respondent finishes. Keep prompting until the respondent says there was nothing else. While recording, underline any unfamiliar terms.

Take a moment to tick all items mentioned spontaneously in the open history questionnaire.

Use this to guide you through the rest of the questionnaire.

5.1.1	Diarrhoea	G
5.1.2	Cough	G
5.1.3	Fever	G
5.1.4	Rash	G
5.1.5	Injury	G
5.1.6	Coma	G
5.1.7	Fit	G
5.1.8	Stiff neck	G
5.1.9	Tetanus	G
5.1.10	Measles	G
5.1.11	Kwashiorkor	G
5.1.12	Marasmus	G
5.1.13	Difficult breathing	G
5.1.14	Rapid breathing	G
5.1.15	Complicated delivery	G
5.1.16	Malformation	G
5.1.17	Multiple birth	G
5.1.18	Very small at birth	G
5.1.19	Very thin	G
5.1.20	Born early	G
5.1.21	Pneumonia	G
5.1.22	Accident	G
5.1.23	Malaria	G
5.1.24	Jaundice	G
5.1.25	Other terms (specify _____)	G

Note: When developing the country-specific questionnaire, local terms likely to be used by respondents should be added to this list.

5.2 What was the length of time the child was ill before he/she died? __ __days
(*Use one month = 28 days to determine the number of months*) __ __months

5.3 Was care sought outside the home while he/she had this illness?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to section 6*)

5.3.1 (*If yes ask:*) Where or from whom did you seek care? *(Record all responses)*

1. Traditional healer . . . . . **G**
2. Religious leader . . . . . **G**
3. Government hospital . . . . . **G**
4. Governmental health centre or clinic . . . . . **G**
5. Community-based practitioner associated with health system including trained birth attendants. . . . . **G**
6. Private physician . . . . . **G**
7. Pharmacy, drug seller, store, market . . . . . **G**
8. Other provider . . . . . **G**
9. Relative, friend (outside household) . . . . . **G**

After respondent finishes prompt: Did you seek care anywhere else? *Keep using this prompt until respondent replies that they did not seek care from anyone else.*

Note: Above categories should be country-specific.

Section 6: Accident

6.1 Did _____ die from an injury, accident, poisoning, bite, burn or drowning?

1. Yes **G** 2. No. **G** 3. Don't know **G**
(*If "No" or "Don't know", go to section 7)*

6.1.1 *(If yes ask):* What kind of injury or accident? *Allow respondent to answer spontaneously. If respondent has difficulty identifying the injury or accident, read the list slowly.*

1. Motor vehicle accident **G**
2. Fall **G**
3. Drowning **G**
4. Poisoning **G**
5. Bite or sting by venomous animals **G**
6. Burn **G**
7. Violence **G**
8. Other injury (specify) _____ **G**

6.1.2 How long did _____ survive after the injury, poisoning, bite, burn or drowning?

1. Died within 24 hours **G**
2. Died 1 day later or more **G**

Section 7: Age determination and reconfirmation

7.1 *Record the child's date of birth from question 4.1* ___/___/___
dd mm yy

Record child's date of death from question 4.2 ___/___/___
dd mm yy

7.2 *Take a moment and calculate the age of the child at the time of death.*
Read out: I have calculated that _____ was __ __ days (or months or years old as appropriate) at the time of death. Is this correct?

If the respondent indicates this is not correct, reconcile the inconsistency by re-checking the child's date of birth and date of death. Make the necessary corrections here and in section 4.

7.3 If it is not possible to reconcile the inconsistency, ask:
How old was _____ at the time of death?

1. 28 days or more **G**
2. less than 28 days **G**

IF CHILD DIED WITHIN 24 HOURS FROM INJURY OR ACCIDENT,
GO TO SECTION 10 – TREATMENT AND RECORDS

IF CHILD WAS LESS THAN 28 DAYS OLD AT THE TIME OF DEATH,
GO TO SECTION 8 – NEONATAL DEATHS

IF CHILD WAS 28 DAYS OLD OR MORE AT THE TIME OF DEATH,
GO TO SECTION 9 – POST-NEONATAL DEATHS

Section 8: Neonatal deaths

8.1 Was the child a singleton or multiple birth?
(*If two or more children are born at the same time, it is counted as a multiple birth, even if one or more of the babies are born dead*).

1. Singleton **G**
2. Multiple **G**

8.2 Did this child's pregnancy end early, on time, or late?

1. Early **G**
2. On time **G**
3. Late **G**
4. Don't know **G**

8.3 Was the late part of the pregnancy, labour or delivery complicated?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 8.4)*

8.3.1.1 *(If yes ask):* What complications occurred during late pregnancy, labour or delivery? (Record all responses)

1. Mother had convulsions **G**
2. Child delivered feet first **G**
3. Excessive bleeding **G**
4. Emergency Caesarean section **G**
5. Multiple delivery **G**
6. Other (specify) _____

8.3.1.2 *(After respondent finishes prompt)*: Was there anything else? (*Keep using this prompt until the respondent replies that there were no other complications.)*

8.4 How many months long was the pregnancy? __ __ months

8.5 Did the waters break before labour or during labour?

1. Before **G** 2. During **G** 3. Waters never broke **G** 4. Don't know **G**
(If waters did not break before, go to question 8.6)

8.5.1 (*If waters broke before labour ask*): How much time before labour did the waters break?

1. Less than one day **G**
2. One day or more **G**

8.6 How much time did the labour and delivery take?
(*Note: labour begins when contractions are no more than 10 minutes apart.*)

1. Less than 12 hours **G**
2. Twelve hours or more **G**

8.7 Were there any bruises or marks of injury on _____'s body at birth?

1. Yes **G** 2. No **G** 3. Don't know **G**

8.8 Did he/she have any malformations at birth?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 8.9)*

8.8.1 *(If yes ask):* Where were there malformations?

1. Head **G**
2. Body **G**
3. Arms/hands **G**
4. Legs/feet **G**

8.8.2 *(After respondent finishes prompt):* Were there malformations anywhere else? (*Keep using this prompt until the respondent replies that there were no malformations anywhere else.*)

8.9 At the time of birth was _____:
(*Read out choices*)

1. Very small? **G**
2. Smaller than usual? **G**
3. About average? **G**
4. Larger than usual? **G**

8.10 Was _____ able to breathe after birth?
(Note: *This does not include gasps or very brief efforts to breathe*)

1. Yes **G**
2. No **G**
3. Don't know **G**

8.11 Was _____ able to suckle (or bottle feed) in a normal way after birth?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.12 Did _____ stop being able to suckle in a normal way?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 8.13*)

8.12.1 *(If yes ask):* How long before he/she died did_____ stop suckling?

1. Less than one day **G**
2. One day or more **G**
3. Don't know **G**

8.12.2 How long after birth did _____ stop suckling?

1. Less than one day **G**
2. One to two days **G**
3. Three to seven days **G**
4. Eight to 14 days **G**
5. Fifteen to 30 days **G**
6. Don't know **G**

8.13 Was _____ able to cry after birth?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.14 Did _____ stop being able to cry?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 8.15*)

8.14.1 *(If yes ask):* How long before he/she died did _____ stop crying?

1. Less than one day **G**
2. One day or more **G**

8.15 During the illness that led to death did _____ have spasms or convulsions?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.16 During the illness that led to death, did he/she become unresponsive/unconscious?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.17 During the illness that led to death, did he/she have a bulging fontanelle?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.18 During the illness that led to death, did he/she have "tetanus" (local words)?

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing the country-specific questionnaire include local terms for tetanus here.

8.19 During the illness that led to death, did he/she have yellow eyes?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.20 During the illness that led to death, did he/she have redness or drainage from the umbilical cord stump?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.21 During the illness that led to death, did he/she have areas of skin that were red and hot?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.22 During the illness that led to death, did he/she have a skin rash with bumps containing pus?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.23 During the illness that led to death, did he/she have a fever?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 8.24*)

8.23.1 *(If fever ask):* How many days did the fever last? . . . . . __ __ days

8.24 During the illness that led to death, did he/she have frequent loose or liquid stools?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.25 During the illness that led to death, did he/she have (local terms for diarrhoea)?

1. Yes **G** 2. No **G** 3. Don't know **G**

(*If "No" or "Don't know", for <u>both</u> questions 8.24 and 8.25, go to question 8.26*)

Note: When preparing country-specific questionnaire include local terms for diarrhoea here.

8.25.1 (*If frequent or liquid stools or local term for diarrhoea, ask*): For how many days did he/she have loose or liquid stools? . . . . . __ __ days

8.25.2 Do you feel that this represented more loose or liquid stools than usual for that child?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.25.3 Was there visible blood in the loose or liquid stools?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.25.4 During the time with loose or liquid stools did the child drink (insert a list of home-made fluids recommended by national CDD program) or ORS?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.26 During the illness that led to death, did _____ have a cough?

1. Yes **G** 2. No **G** 3. Don't know **G**

(*If "No" or "Don't know", go to question 8.27*)

8.26.1 *(If yes ask):* For how many days did the cough last? . . . . . __ __days

8.27 During the illness that led to death, did _____ have difficult breathing?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 8.2.8*)

8.27.1 *(If yes ask):* For how many days did the difficult breathing last?. . . . __ __ days

8.28 During the illness that led to death, did the child have fast breathing?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 8.29)*

8.28.1 *(If yes ask):* For how many days did the fast breathing last *?* . . . . . __ __ days

8.29 During the illness that led to death, did _____ ever stop breathing for a long time, and start again?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.30 During the illness that led to death, did he/she have indrawing of the chest?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.31 During the illness that led to death, did he/she have noisy breathing? (*Demonstrate each sound*)

8.31.1 Stridor . . . . . 1. Yes **G**
2. No **G**
3. Don't know **G**

8.31.2 Grunting . . . . . 1. Yes **G**
2. No **G**
3. Don't know **G**

8.31.3 Wheezing . . . . . 1. Yes **G**
2. No **G**
3. Don't know **G**

8.32 During the illness that led to death, did his/her nostrils flare with breathing?

1. Yes **G**
2. No **G**
3. Don't know **G**

8.33 During the illness that led to death, did _____ have pneumonia (local terms)?

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing the country-specific questionnaire, include local term for pneumonia.

GO TO SECTION 10

Section 9: Post-neonatal deaths

9.1 During the illness that led to death, did he/she have a fever?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 9.2)*

9.1.1 *(If fever ask):* How many days did the fever last? . . . . . .__ __ days

9.2 During the illness that led to death, did _____ have frequent loose or liquid stools?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.3 During the illness that led to death, did he/she have (local terms for diarrhoea)?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", for both questions 9.2 and 9.3, go to question 9.4*)

9.3.1 (*If frequent or loose stools or local terms for diarrhoea ask*):
For how many days did he/she have loose or liquid stools? . . . . __ __ days

Note: When preparing the country-specific questionnaire, include local terms for diarrhoea.

9.3.2 Was there visible blood in the loose or liquid stools?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.3.3 During the time with the loose or liquid stools, did the child drink (*when preparing the country-specific questionnaire, insert a list of home-made fluids recommended by the National CDD program*) or ORS?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.4 During the illness that led to death, did the child have a cough?

1.Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or "Don't know", go to question 9.5*)

9.4.1 *(If yes ask):* For how many days did the cough last? . . . . . __ __days

9.4.2 Was the cough very severe?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.5 During the illness that led to death, did _____ have difficult breathing?

1.Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or Don't know", go to question 9.6*)

9.5.1 (*If yes ask*): For how many days did the difficult breathing last? __ __ days

9.6 During the illness that led to death, did _____ have fast breathing?

1.Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or Don't know", go to question 9.7)*

9.6.1 *(If yes ask):* For how many days did the fast breathing last? . . . . __ __ days

9.7 During the illness that led to death, did he/she have indrawing of the chest?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.8 During the illness that led to death, did he/she have noisy breathing? (*Demonstrate each sound*)

9.8.1 Stridor	1.	Yes	**G**
	2.	No	**G**
	3.	Don't know	**G**
9.8.2 Grunting	1.	Yes	**G**
	2.	No	**G**
	3.	Don't know	**G**
9.8.3 Wheezing	1.	Yes	**G**
	2.	No	**G**
	3.	Don't know	**G**

9.9 During the illness that led to death, did his/her nostrils flare with breathing?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.10 During the illness that led to death, did _____ have pneumonia?

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing country-specific questionnaires include local terms for pneumonia here.

9.11 Did _____ experience any generalized convulsions/fits during the illness that led to death?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.12 Was _____ unconscious during the illness that led to death?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.13 At any time during the illness that led to death, did _____ stop being able to grasp?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or Don't know", go to question 9.14)*

9.13.1 *(If yes, ask):* How long before he/she died did the child stop being able to grasp?

1. Less than 12 hours **G**
2. 12 hours or more **G**

9.14 At any time during the illness that led to death, did _____ stop being able to respond to a voice?

1. Yes **G** 2. No **G** 3. Don't know **G**
(*If "No" or Don't know", go to question 9.15)*

9.14.1 *(If yes,ask):* How long before he/she died did the child stop being able to respond to a voice?

1. Less than 12 hours **G**
2. 12 hours or more **G**

9.15 At any time during the illness that led to death, did the child stop being able to follow movements with their eyes?

1. Yes **G** 2. No **G** 3. Don't know **G**
(If "No" or Don't know", go to question 9.16)

9.15.1 *(If yes, ask):* How long before he/she died did the child stop being able to follow movements with their eyes?

1. Less than 12 hours **G**
2. 12 hours or more **G**

9.16 Did _____ have a stiff neck during the illness that led to death?
(*Demonstrate*)

1. Yes **G**
2. No **G**
3. Don't know **G**

9.17 Did _____ have a bulging fontanelle during the illness that led to death?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.18 During the month before he/she died, did _____ have a skin rash?

1. Yes **G** 2. No **G** 3. Don't know **G**
(If "No" or Don't know", go to question 9.19)

9.18.1 (*If yes, ask*) Was the rash all over _____'s body?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.18.2 Was the rash also on _____'s face?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.18.3 How many days did the rash last? . . . __ __ days

9.18.4 Did the rash have blisters containing clear fluid?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.18.5 Did the skin crack/split or peel after the rash started?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.18.6 Was this illness "measles"?

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing country-specific questionnaire include local term for measles.

9.19 During the illness that led to death, did _____ become very thin?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.20 During the illness that led to death, did _____ have swollen legs or feet?

1. Yes **G** 2. No **G** 3. Don't know **G**
   (If "No" or Don't know", go to question 9.21)

9.20.1 *(If yes, ask):* How long did the swelling last? Number of weeks __ __

9.21 During the illness that led to death, did _____'s skin flake off in patches?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.22 Did _____'s hair change in colour to a reddish (or yellowish) colour?

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing country-specific questionnaire, terms for colour to be locally adapted.

9.23 Did _____ have "kwashiorkor" during the month before he/she died?

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing country-specific questionnaire, local terms for kwashiorkor should be included.

9.24 Did _____ have "marasmus" during the month before he/she died?

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing country-specific questionnaire, local terms for marasmus should be included.

9.25 During the illness that led to death, did _____ suffer from "lack of blood" or "pallor"?

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing country-specific questionnaire, local terms for "lack of blood" or "pallor" should be included.

9.26 During the illness that led to death, did_____ have pale palms?
(*Show photo if possible*)

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing country-specific questionnaire, local terms for "pale palms"should be included.

9.27 During the illness that led to death, did _____ have white nails?
(*Show photo if possible*)

1. Yes **G**
2. No **G**
3. Don't know **G**

Note: When preparing country-specific questionnaire local terms for "white nails" should be included here.

9.28 During the illness that led to death, did _____ have swellings in the armpits?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.29 During the illness that led to death, did _____ have swellings in the groin?

1. Yes **G**
2. No **G**
3. Don't know **G**

9.30 During the illness that led to death, did _____ have a whitish rash inside the mouth or on the tongue?

1. Yes **G**
2. No **G**
3. Don't know **G**

Section 10: Treatment and records

I would now like to ask a few questions about any drugs _____ may have received during the illness that led to death.

10.1 Did _____ receive any of the following?

10.1.1	Antibiotics	1.	Yes	G
		2.	No	G
		3.	Don't know	G
10.1.2	Chloroquine	1.	Yes	G
		2.	No	G
		3.	Don't know	G
10.1.3	Aspirin	1.	Yes	G
		2.	No	G
		3.	Don't know	G

10.2 Do you have any health records that belonged to _____?

1. Yes G 2. No G 3. Don't know G
(If "No" or Don't know", go to question 10.5)

10.2.1 (*If yes ask*): Can I see the health records?

1. Yes G 2. No G 3. Don't know G
(If "No" or Don't know", go to question 10.5)

If respondent allows you to see the health records, transcribe all the entries within the 12 months before the child died.

10.3 Weights (most recent two)

10.3.1 Record the dates of the most recent weight two weights
1. __/__/__ (dd/mm/yy)
2. __/__/__ (dd/mm/yy)

10.3.2 Record the most recent two weights . . 1. kg _ _._
2. kg _ _._

10.4 Medical notes

10.4.1 Record the date of the last note. . . __/__/__ (dd/mm/yy)
10.4.2 Transcribe the note _____
_____
_____
_____

10.5 Was a death certificate issued?

1. Yes **G** 2. No **G** 3. Don't know **G**
(If "No" or Don't know", go to question 10.7)

INSTRUCTIONS TO INTERVIEWER - Ask to see the death certificate and record whether you have been able to see it.

10.5.1 Able to see death certificate?

1. Yes **G** 2. No **G**
(*If "No", go to question 10.7*)

10.6 Record the immediate cause of death from the certificate _____

10.6.1 Record the first underlying cause of death from the certificate _____

10.6.2 Record the second underlying cause of death from the certificate _____

10.6.3 Record the third underlying cause of death from the certificate _____

10.6.4 Record the contributing cause(s) of death from the certificate _____

Now I would like to ask a few questions about the child's mother.

10.7 Has the child's (biological) mother ever been tested for "HIV"?

1. Yes **G** 2. No **G** 3. Don't know **G**
(If "No" or Don't know", go to question 10.8)

10.7.1 (*If yes ask*)*:* Was the "HIV" test ever positive?

1. Yes **G**
2. No **G**
3. Don't know **G**

10.8 Has _____’s (biological) mother ever been told she had “AIDS” by a health worker?

1. Yes **G**
2. No **G**
3. Don’t know **G**

END OF INTERVIEW

THANK RESPONDENT(S) FOR THEIR COOPERATION
